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14. ABSTRACT The Regional Anesthesia (RA) and Central Venous Access (CVA) mixed reality simulators are ready to be delivered to DoD, both exceeding original specifications. See http://simulation.health.ufl.edu/research/ra_sim.wmv . Preliminary data from a new study of the CVA simulator indicates that an integrated tutor may be non-inferior to a human instructor, opening the possibility of self-study and self-debriefing which in turn facilitate competency-based, instead of time-based simulation training. A manuscript describing a study showing that visual augmentation, whether in real time or delayed, improves learning and performance, has been accepted pending revision by <i>Anesthesia & Analgesia</i> . A software development kit (SDK) has been started that will allow third parties to develop new simulators for procedures beyond the 5 deliverables to DoD that include an ultrasound probe and a needle.					
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Table of Contents

	<u>Page</u>
1. Introduction.....	2
2. Keywords.....	2
3. Accomplishments.....	3
4. Impact.....	43
5. Changes/Problems.....	45
6. Products.....	45
7. Participants & Other Collaborating Organizations.....	52
8. Special Reporting Requirements.....	N/A
9. Appendices.....	N/A

**ANNUAL REPORT
(Year 3 of 3 - Phase I)**

A Modular Set of Mixed Reality Simulators for “Blind” and Guided Procedures
Award W81XWH-14-1-0113

Reporting Period: 8/1/2016 – 7/31/2017 (**Year 3**)

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This annual report covers only the 3-year (8/1/2014 – 7/31/17) Phase I of award W81XWH-14-1-0113 “A Modular Set of Mixed Reality Simulators for “Blind” and Guided Procedures”. It does NOT cover the awarded 2-year (8/1/2017 – 7/31/2019) Phase II extension period.

INTRODUCTION:

We are ultimately developing and delivering a modular set of five mixed reality/augmented reality (AR) simulators, each for a different application from a set of five “blind” and guided medical procedures: (1) Regional Anesthesia (RA), (2) Central Venous Access (CVA), (3) External Ventricular Drain (EVD; aka Ventriculostomy), (4) Chest Tube Insertion (CTI) and (5) TransRectal UltraSound (TRUS)-Imaged, Manually-Guided Needle Biopsy of the Prostate. The AR is through visual augmentation, i.e., providing 3D, real-time, color visualization of the relevant anatomy, tools, cognitive aids and implements. Our purpose is to provide deployed and Stateside medical military personnel and also civilian reservists and clinicians compact, lightweight, turnkey simulators designed to work in austere environments. These highly-portable/deployable simulators are designed to provide the ability to acquire/maintain skills in medical procedures, some of which may be specific to military medicine and therefore unfamiliar to reservists who practice primarily civilian medicine. The ultimate purpose is to provide through the military medical personnel trained via our simulators safer and better quality care (as measured by our proposed patient outcomes study) to US military personnel (deployed and Stateside) and veterans. The scope of this research is deliberately wide; because the simulators are anatomic, they are not specific to military medical needs or protocols and can be readily repurposed for civilian medical training needs too. In addition, the modular nature of the system design (including the modular stand) will allow ready implementation of new mixed/augmented reality simulators beyond the original five to be delivered to DoD.

KEYWORDS:

Integrated tutor, Plug-ins, SMARTS (System of Modular Augmented Reality Tracking Simulators) rapid simulator development platform, Needs assessment, Outcomes studies (learning, behavior, results, ROI), Augmented reality procedural simulators, Mixed reality, Modular, Turnkey, Ultrasound imaging, Visual augmentation

ACCOMPLISHMENTS:

Major Goals and Objectives

The major goals and objectives for Phase I are:

- Needs assessment for a set of 5 mixed reality procedural simulators:
 - Regional Anesthesia (RA)
 - Central Venous Access (CVA)
 - External Ventricular Drain (EVD; aka Ventriculostomy)
 - Chest Tube Insertion (CTI)
 - Trans Rectal Ultra Sound (TRUS)-Imaged, Manually-Guided Needle Biopsy of the Prostate (exchanged for the FAST trainer with approval from DoD)
- Build/integrate simulated US imaging into modular simulator design
- Design/build/evaluate/refine modular stand that will be common to the 5 different simulators (and other potential future simulators) to be delivered to DoD
- Design 4 outcome studies (based on the Kirkpatrick levels) with UF IRB and also HRPO oversight and approval:
 - Learning (Kirkpatrick Level 2)
 - Transfer to Clinical Practice (Kirkpatrick Level 3)
 - Patient Outcomes (Kirkpatrick Level 4)
 - Return on Investment – ROI (“Kirkpatrick Level 5”, aka Kirkpatrick/Phillips)
- Design, build, quality control, deliver to DoD during Phase I:
 - Phase I Regional Anesthesia (RA) simulator
 - Phase I Central Venous Access (CVA) simulator

Accomplishments Relative to Major Goals & Objectives

- Needs assessment has been completed for the RA and CVA simulators. Needs assessment is 80% complete for the EVD simulator and 50% complete for the prostate biopsy simulator. The needs assessment for the chest tube insertion simulator is 70% done.
- Simulated Ultrasound (US) imaging has been implemented and integrated into the modular simulator design. Status: 100% completed and deployed; beta tested at 5 military sites (Naval Medical Center, San Diego; Walter Reed National Military Medical Center, Bethesda; Brooke Army Medical Center, San Antonio; Wilmington Delaware VA Medical Center; Fort Sam Houston). A simulated US probe was designed to house a 6-DoF tracking magnetic sensor and 3D printed. The simulated US image is generated *on-the-fly* (in real time) according to fundamental principles, from the intersection of an insonation plane with the 3D object being insonated to create a 2D cross-section. A virtual representation of the US probe was also created in the 3D visualization; a thin red sheet emanating from the long axis midline of the US probe represents the insonation plane and makes the invisible insonation plane visible in the 3D visualization. Pressure sensors (actually force sensitive resistors, FSRs) are placed on the face of the simulated US probe and help to determine how hard the user is pressing the US probe onto the skin. Based on the applied pressure/force, collapsible structures such as veins are seen to deform in the simulated US image and also in the 3D visualization. In addition, anisotropy was implemented in the simulated US image. Anisotropy is the property where depending on the angle of incidence of the insonation to the surface being insonated all or most of the US energy bounces away from, instead of back towards the probe, rendering objects that are in the insonation plane “invisible” or degrading their image in the simulated US image. The online video at http://simulation.health.ufl.edu/research/ra_sim.wmv shows how simulated ultrasound (US) imaging has been implemented and integrated into the modular AR simulator

design. See for example the video frames from 0:09 to 0:15. The simulated US image can occupy the entire screen or be combined with a 3D, color, real-time visualization. Anisotropy can be toggled on or off via the simulator user interface (UI) implemented on a right hand column on the screen of the laptop computer. Anisotropy can be readily turned off when using the simulator in “training wheels” mode with novices.

- A SMARTS (System of Modular Augmented Reality Tracking Simulators) modular stand has been successfully designed, built and demonstrated at multiple venues and meetings. Status: 100% completed and deployed; beta tested at 5 military sites. See photo in Figure 1 below that shows a completed modular stand with a modular upper thorax anatomical block installed. Figures 2a – 2c show three other anatomical blocks that will mount onto the modular stand. Figure 2d shows the modular stand by itself. The modular stand holds a tracker unit at the bottom. The anatomical module base has a mechanical indexing groove that indexes and registers the anatomical block module to the tracker on the underside of the modular stand. The legs of the modular stand fold for compact packing in its mil spec padded transport case (Thermodyne initially, now Pelican as we have had failures with the Thermodyne case).



Figure 1. The modular stand is on the right of the photo. It is shown in the thoracic regional anesthesia simulator configuration, i.e., with an RA anatomical module representing the posterior upper thorax snapped and indexed into the modular stand. Thoracic paravertebral blocks (TPVBs) and other regional anesthesia techniques (like epidurals) can be practiced, acquired and maintained via this completed RA simulator. Towards the middle of the photo, the tool tray (black sponge with precision cutouts for holding tracked tools) includes the simulated ultrasound (US) probe on the right (off white color). A Tangible User Interface (TUI) for controlling the virtual camera is in the middle of the sponge tray (white rectangle with blue button). The TUI is fitted with a 6-DoF sensor that allows the virtual camera to be intuitively controlled by the user along 6-DoF. The blue button when pressed makes the virtual camera follow the TUI in space as the TUI is moved by the user. The user observes the 3D visualization on the laptop computer screen in real time to control the virtual camera position. When the user is satisfied with the virtual camera position and orientation, i.e., the perspective of the 3D visualization, the blue button on the TUI is released. On the left of the tool tray, three items are placed horizontally. The top item is a tracked needle encased in a protective sheath to protect users from its sharp tip. In the middle is a syringe for use with the needle. At the bottom is a marker pen that is used to mark the simulated skin when using US imaging assistance. At the left of the picture is a generic laptop (Acer) purchased at Best Buy with standard CPU, RAM, video RAM and graphics card (i.e., not a high end laptop). We have since converted to a Microsoft Surface as our standard laptop. The computer is shown sitting on top of an electronics box (that we also call a white box).

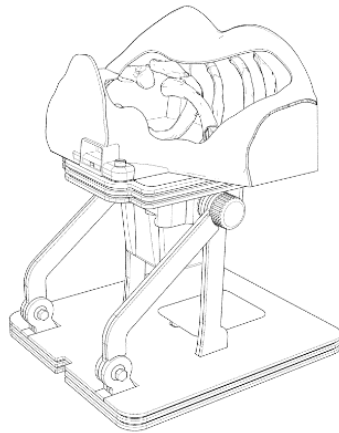


Figure 2a. Left CAD drawing: CVA Module on Modular Stand with Quick Release Latch; Right photograph: 3D printed anatomically correct shells, the one on the left has been painted and includes a puncturable skin that feels like skin. The one on the right has just been received from the 3D print vendor; the indexing plate has been rotated by 90° in the new print based on user feedback.

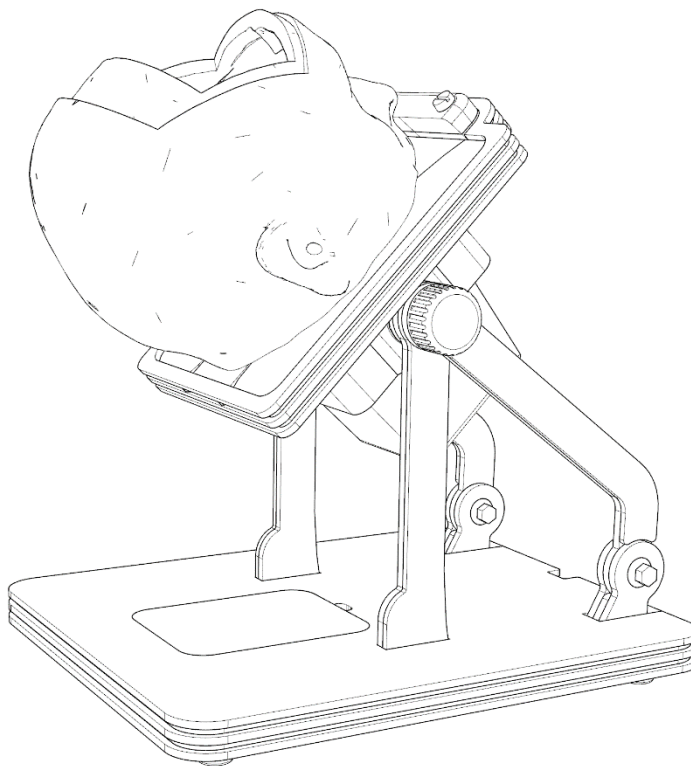


Figure 2b. External Ventricular Drain (EVD; a.k.a. ventriculostomy) Module on Modular Stand

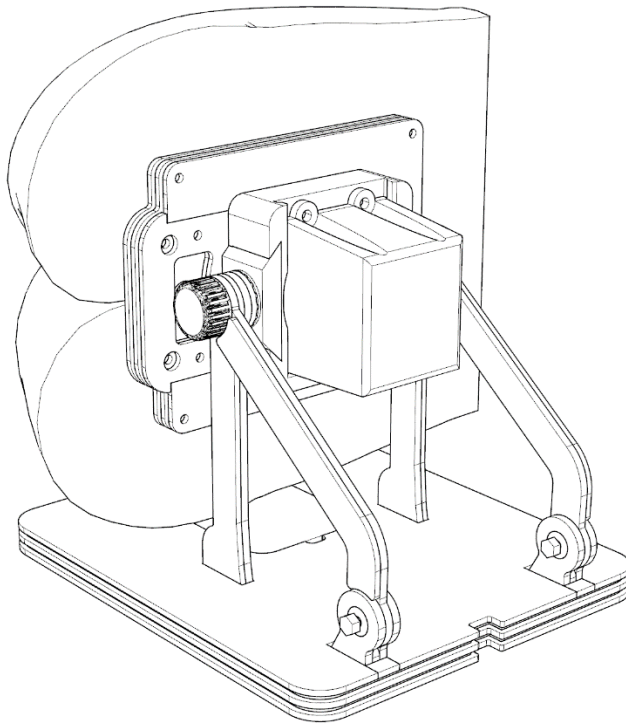


Figure 2c. TRUS-Guided Manual Prostate Biopsy Module on Modular Stand with Quick Release Latch

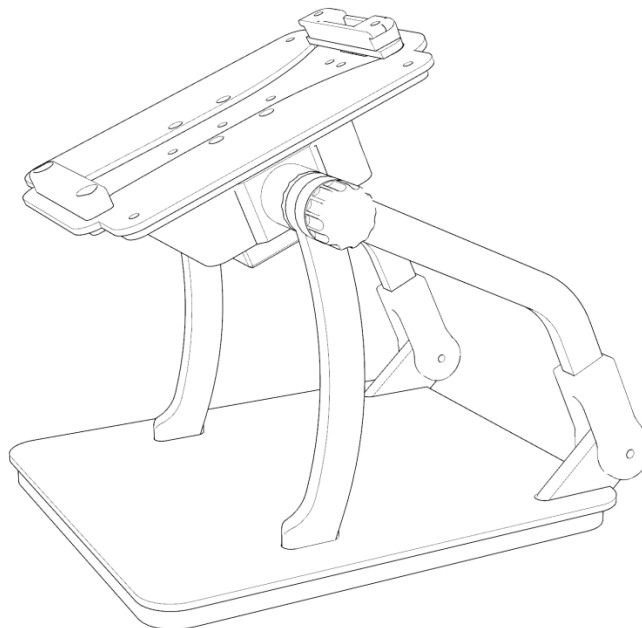
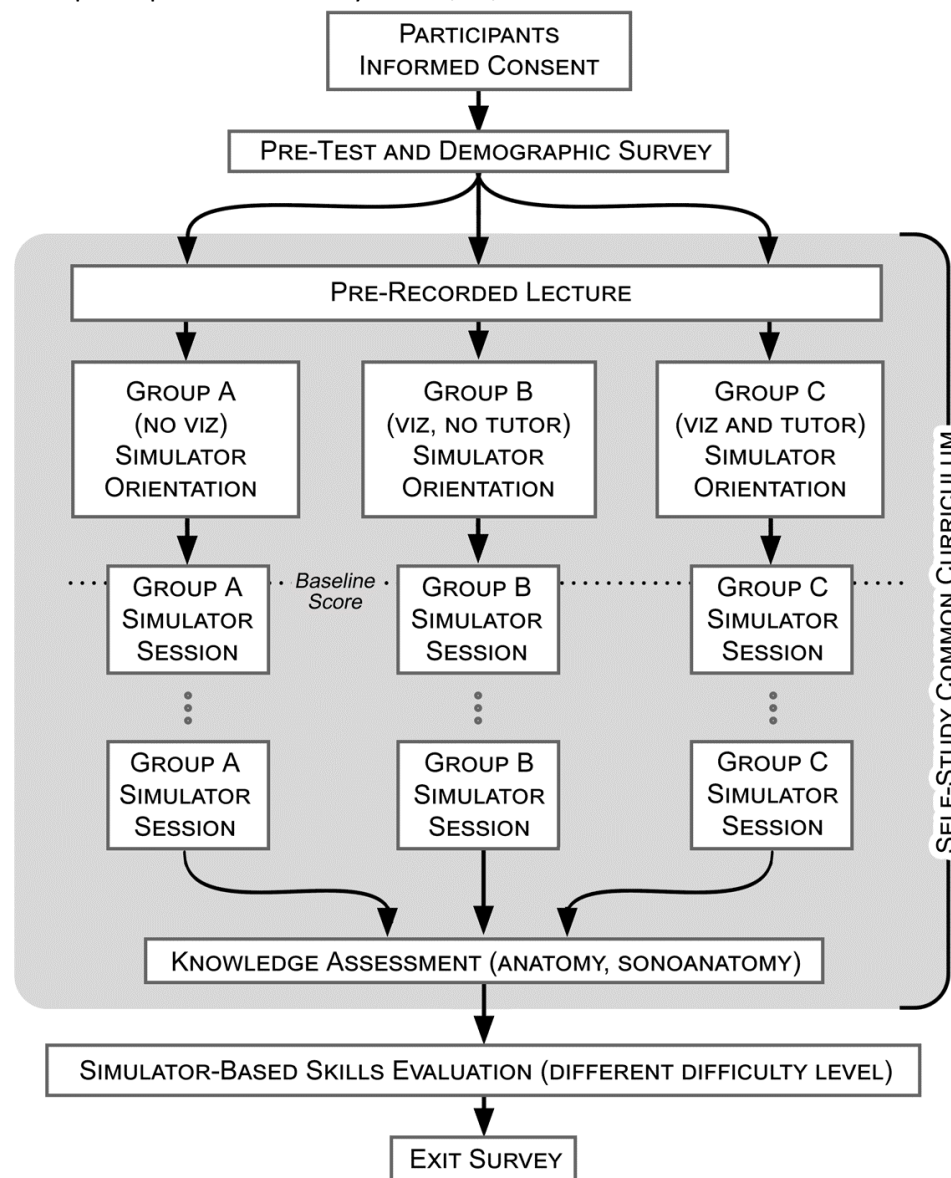


Figure 2d. The modular stand without an anatomical block and the indexing groove visible.

- Four outcome studies (4 total: 3 learning outcome, 1 patient outcome) are currently in various stages of completion)
 - UF IRB02 Approval Number 2014-U-0658. HRPO Log Number A-18036. RA simulator. A learning outcome study (per flowchart below) that investigates whether training with the RA simulator affects skill in performing thoracic paravertebral blocks (TPVB) had already been approved by UF IRB 02 prior to the 8/1/14 start of award W81XWH-14-1-0113 and was subsequently also approved by HRPO on 7/31/15. A revision to 2014-U-0658 was approved by IRB-02 on 4/28/2016. Continuing review of 2014-U-0658 was approved by IRB-02 on 6/3/2016 and subsequent revision was approved 7/11/2016. First participant of the study occurred on 6/21/2016. Seventeen anesthesia residents have participated in the study as of 8/22/17.



- UF IRB02 Approval Number **2013**-U-1025. CVA simulator. A third learning outcome study for the CVA simulator has been completed. The study demonstrated that visual augmentation in the form of color, 3D visualization significantly improved performance

scores (automatically and objectively generated by the simulator), irrespective of whether the visualization is in real-time (i.e., viewed while performing the simulated procedure) or delayed (viewed after performing the simulated procedure). The study results have been accepted for peer-reviewed publication by the journal *Anesthesia & Analgesia* pending minor revision as: Sappenfield JW, Smith WB, Cooper LA, Lizdas DE, Gonsalves D, Gravenstein N, Lampotang S, Robinson AR: Visualization Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator. DoD support of the study has been acknowledged in the manuscript.

- IRB201601147 – Mixed Reality Simulation Training for Central Venous Access (CVA): An Analysis of Retrospective Patient Outcomes. CVA Simulator: Retrospective Study of Patient Outcomes at UF Health – Protocol approved by UFIRB 01 on 9/9/16. Revision submitted and approved on 2/14/17 to add practitioner experience level and the hospital location to our requested dataset. Revision submitted and approved to add new study coordinator, Desmond Zeng. Initial data set from UF Health in Gainesville has been obtained on 4/12/17. We plan on obtaining data from UF Health in Jacksonville and expanding range of data collection dates.
- IRB201600595 – Small Form Factor, Modular, DoD CVA Sim: Learning Outcome Study This between-groups study will compare performance scores on the CVA simulator to determine if self-training and self-debriefing via an integrated tutor is non-inferior to training provided by an average human instructor. An integrated tutor for the CVA simulator had to be built first to be able to start the study. UF IRB02 approval was obtained on 2/20/17. Following successful development of an integrated tutor, we began assessing subjects. 4 residents have completed instruction from the integrated tutor and 6 residents have received human instruction from 2 different human instructors (anesthesiologists).

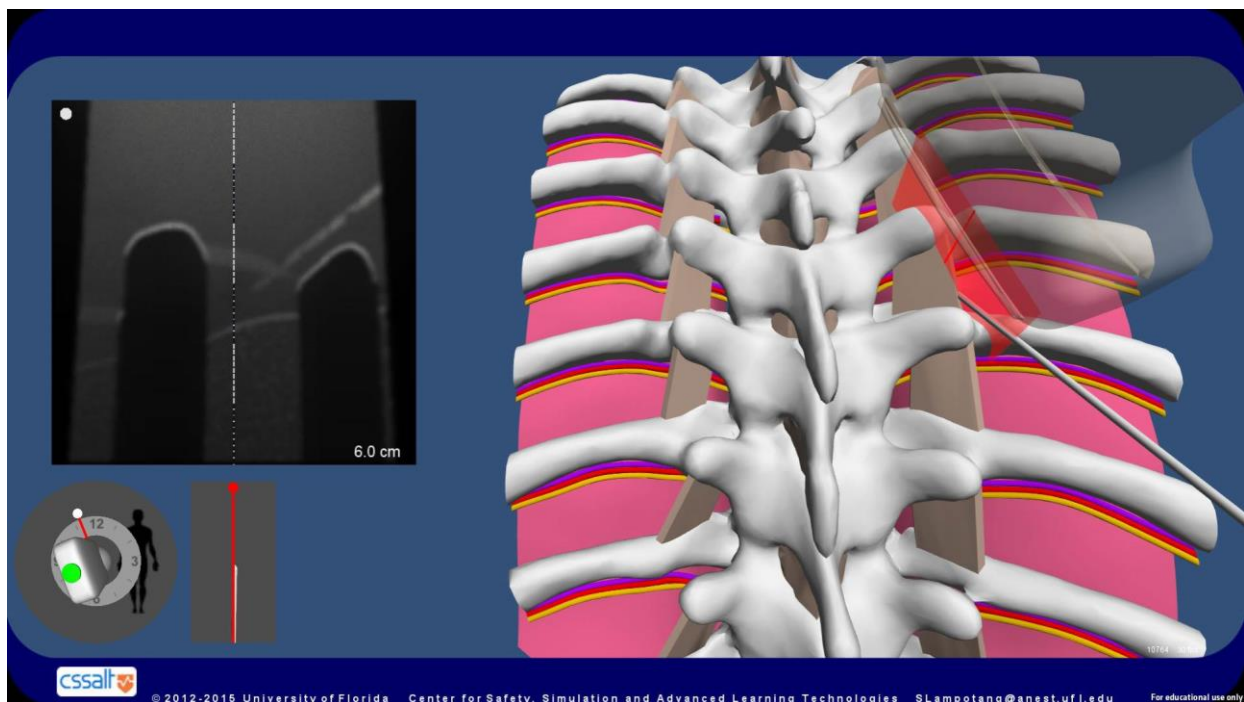


Figure 3. The development of a modified thoracic paravertebral block (TPVB) technique was facilitated by the 3D visual augmentation (visualization) provided by the simulator. The tracked needle is seen in

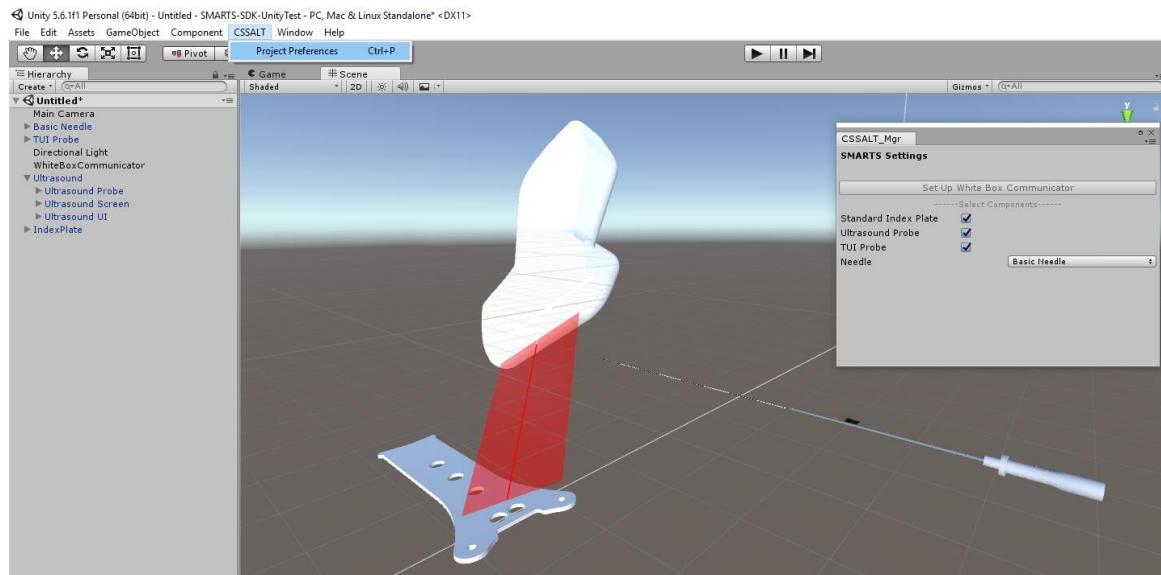
the gray scale simulated US image at the top left of the figure. The two ribs cast dark shadows. The ligament is visible on top of the lung (both structures span the two ribs) in the simulated ultrasound image. The 3D visualization is on the right of the picture and its perspective is controlled by the user or instructor via a virtual camera TUI. A phantom of the US probe based on the actual 6-DoF position of the simulated and tracked physical US probe is also visible in the 3D visualization.

- We have started the process of reconfiguring the entry fields in our Electronic Medical Record (EPIC) to allow us to collect data regarding central venous access procedures and associated complications such as inadvertent pneumothorax and arterial puncture for the Phase II patient outcome studies.
- The Phase I RA simulator is ready (ahead of schedule) and has been beta tested by 5 military medical institutions and subject matter experts (SMEs). 100% completed; target and deliverable exceeded. See the online video at http://simulation.health.ufl.edu/research/ra_sim.wmv
- The Phase I CVA simulator (as defined in the original proposal, i.e., without an integrated tutor) was completed before the end of Year 2 (also ahead of schedule) and was also beta tested at 5 military medical institutions and SMEs. 100% completed.

Accomplishments Above and Beyond Original Specific Deliverables

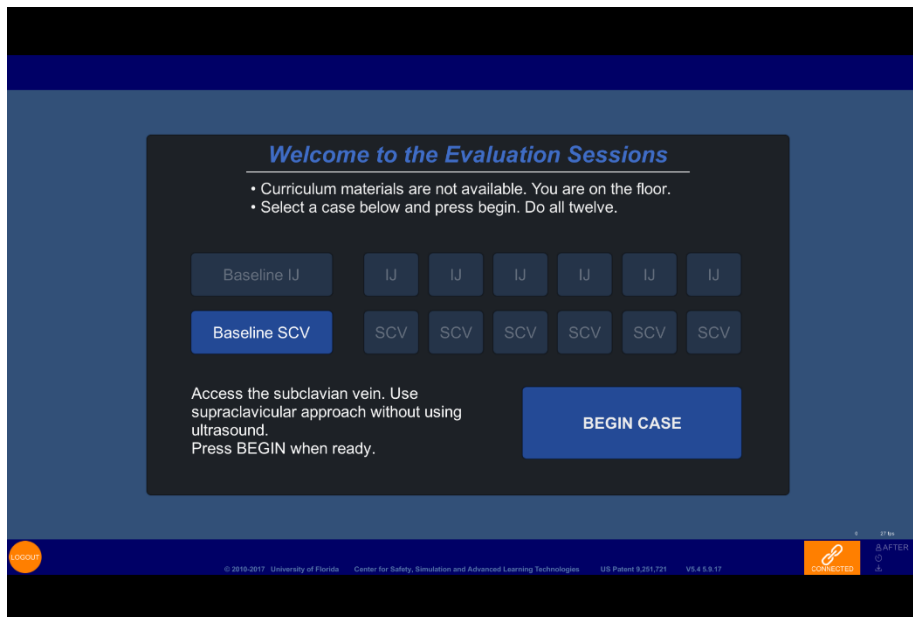
Year 3

1. **SMARTS SDK:** We have created a Software Development Kit (SDK) for our modular mixed reality platform that allows clients outside our lab to build custom simulations using our hardware and software platform. The SDK process required code standardization and documentation. This process yielded improved and optimized software. The SDK is currently in alpha stage development and is being used internally in our lab for new simulators for different procedures.



This Unity editor window is part of the SMARTS SDK. The window instantiates virtual SMARTS tracked tools and establishes hardware connections with a single click.

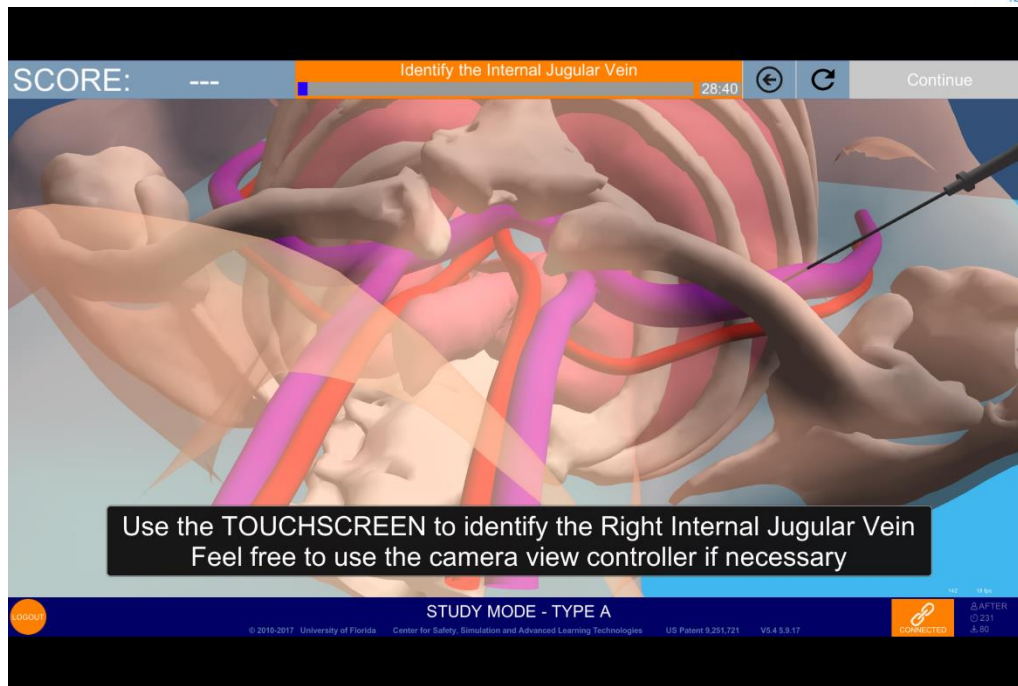
2. **CVA Integrated Tutor Redesign:** We improved our pedagogy and approach to SMARTS integrated tutors. We redesigned the CVA integrated tutor to be responsive and require user engagement, replacing passive video content whenever possible. The curriculum was divided into discrete learning objects. The user learns from performance of small constructivist skills exercises that re-purpose as much as possible discrete, reusable learning objects. The trainee is directed to basic skills exercises if the user's performance in certain tasks did not reach a competency threshold. We added text-to-speech to procedural practice modes so that the user's attention can remain on the simulated patient instead of reading text-based instructions on the computer screen. The performance score is used to select constructivist skills exercises for the user to repeat, or present new basic skills exercises as needed. The skills exercises are designed to be reusable in other simulators. This architecture will be included in the SDK.



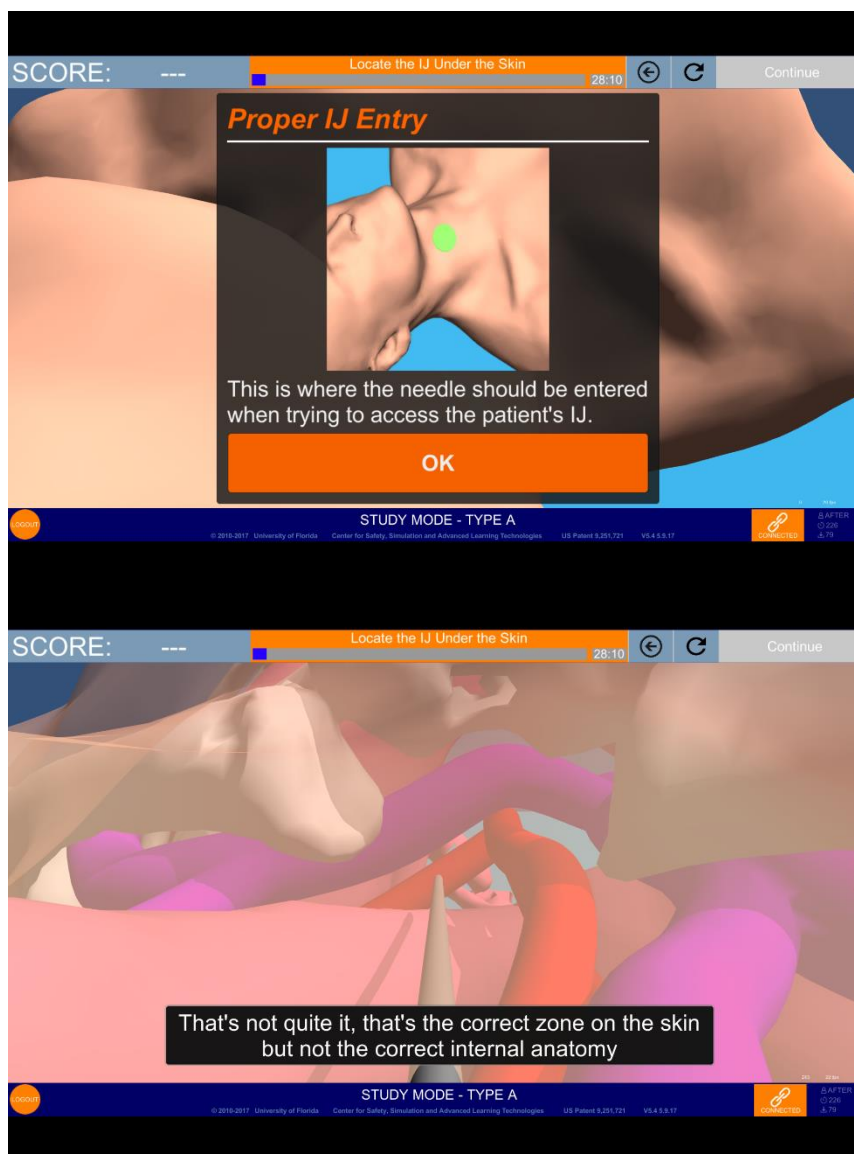
During the CVA study, the participant is first directed to obtain baseline scores.



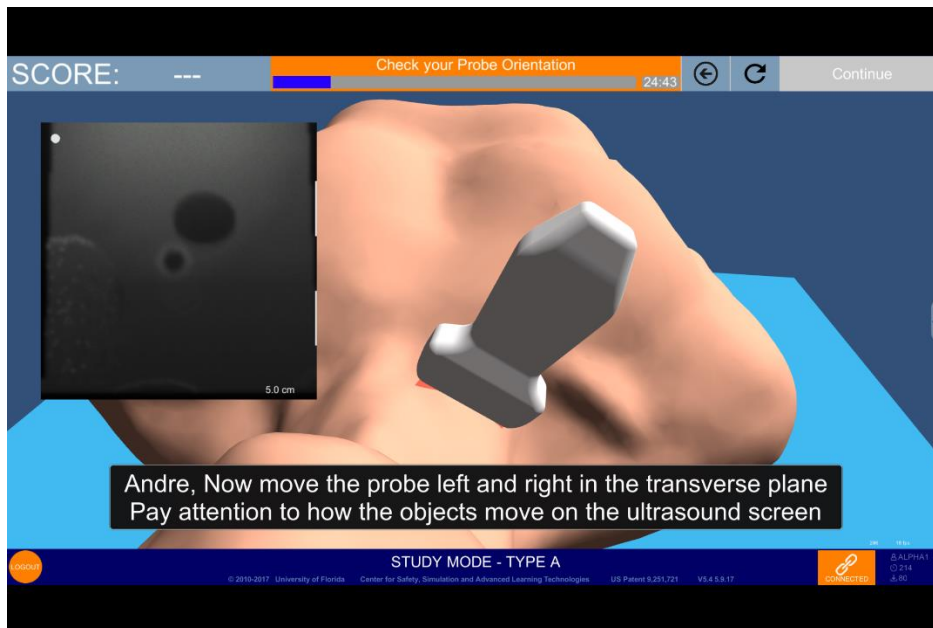
A screen capture of the CVA Integrated Tutor “Progress Widget” expanded to show available steps. Each step is a learning object. The steps and categories are determined by the Integrated Tutor Editor and can be quickly changed.



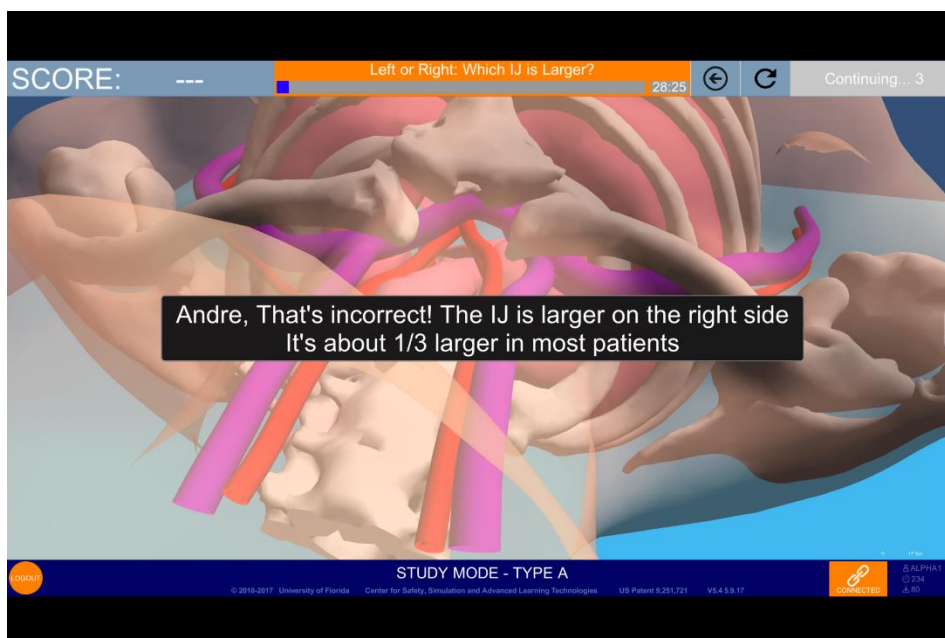
The integrated tutor requests user interaction whenever possible to keep the user active and engaged.



These two screenshots show examples of a skills exercise that teaches the risk of dangerous areas that are very close to safe zones.



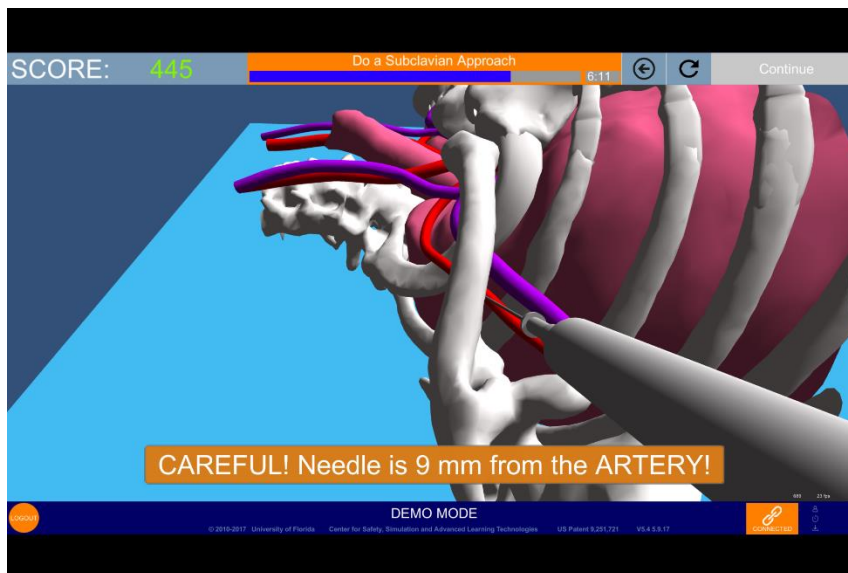
A skills exercise for the US Probe orientation video. Note that the STUDY mode is clearly visible at the bottom of the screen.



Useful feedback is provided with the user's name for retention. The user's name is entered by the user when logging in to start a training session.



During this practice session, the 3D visualization is turned off. The integrated tutor also audibles the text message so users do not need to take their eyes off their task to read the displayed instructions.



The 3D view is automatically turned on to show users how close they are to causing injury, and the message shown is also heard by the participant via a text to speech engine.

SCORE: 388 Do a Subclavian Approach 6:11 Continue

Filename: CVA-2017-08-09_04-17-46-PM.txt
 Participant:
 Group:
 Comments:

Score: 388.2 out of 600 (64.7%)
 Approach: Subclavian
 Seconds to obtain venous access: 20.0
 No Arterial injury, but close enough for a safety penalty.
 Attempts: 2
 Needle trajectory close to lung when the skin was punctured.
 Constantly pull on the syringe plunger for immediate flashback.
 CVA Scoring Algorithm Version 5.1, August 2017

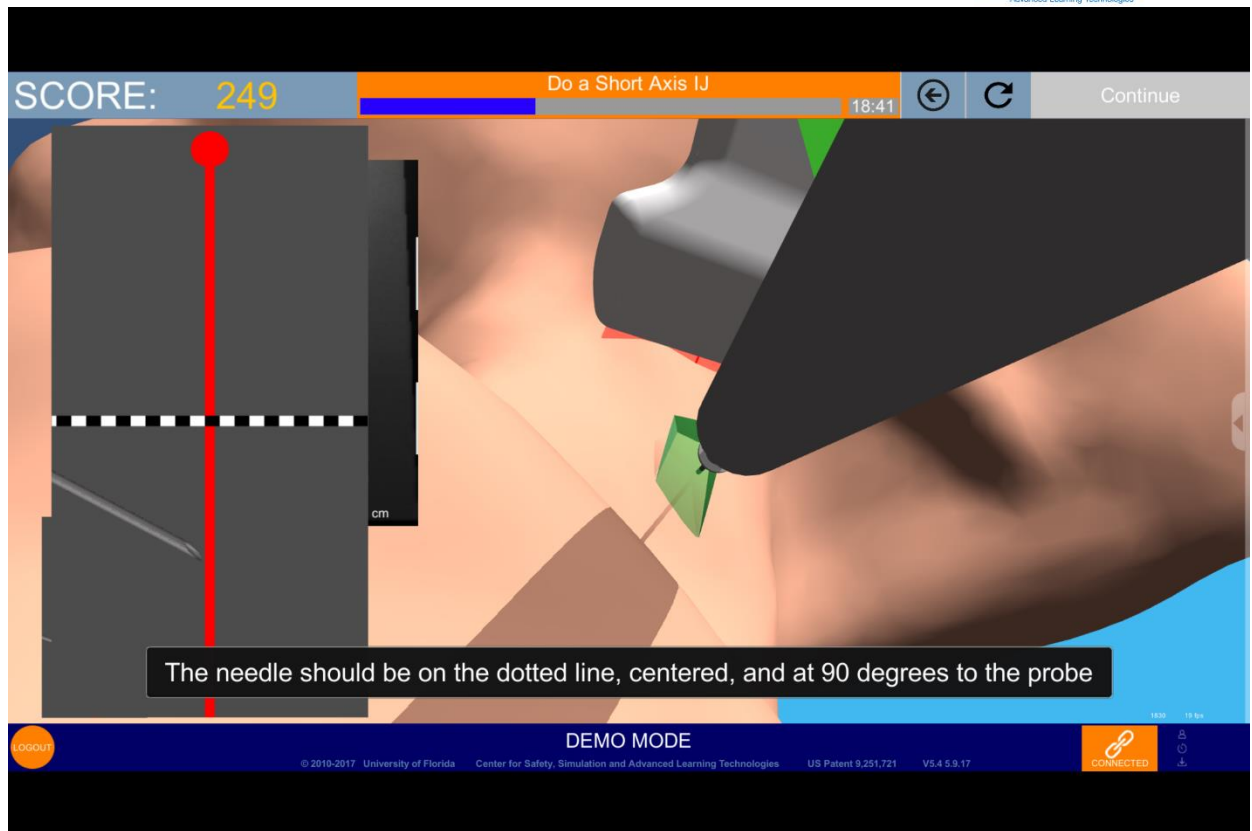
[NEXT] [REPLAY]

DEMO MODE
 © 2010-2017 University of Florida Center for Safety, Simulation and Advanced Learning Technologies US Patent 9,251,721 V5.4 5.9.17

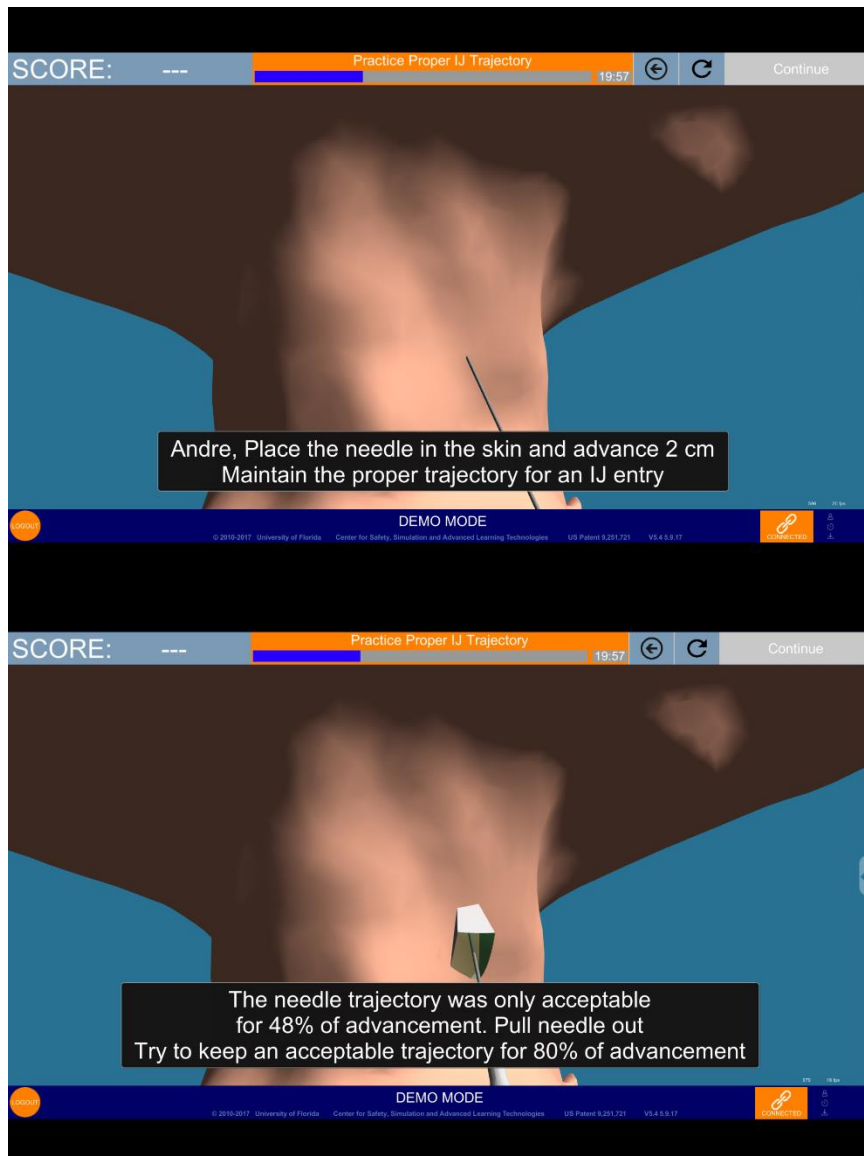
This score report contains feedback that is useful for self-debriefing, and will most likely suggest a foundational basic skills exercise when the user selects “next”. The “Continue” button in the upper right is unavailable because the user needs more practice.

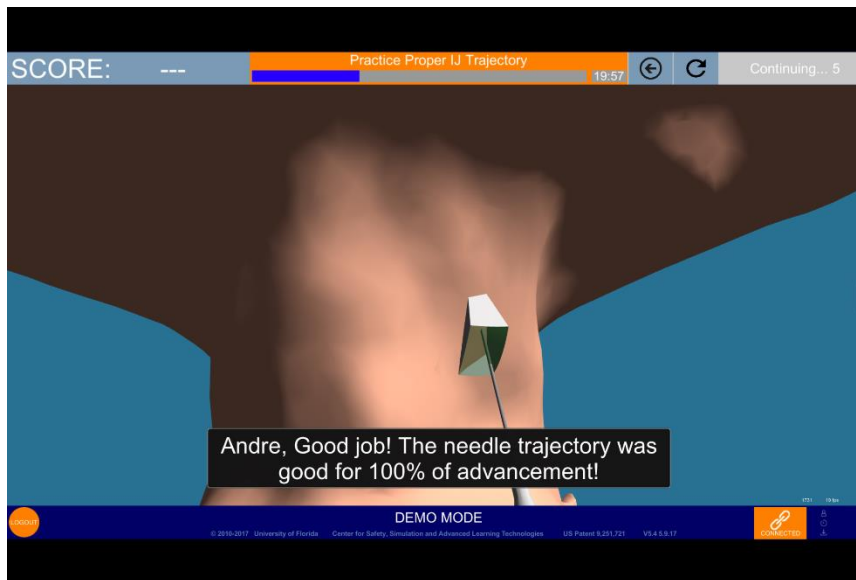


This basic skills exercise focuses users on properly identifying anatomical landmarks.



This skills exercise helps the user align the needle with the center of the probe during an out of plane technique.





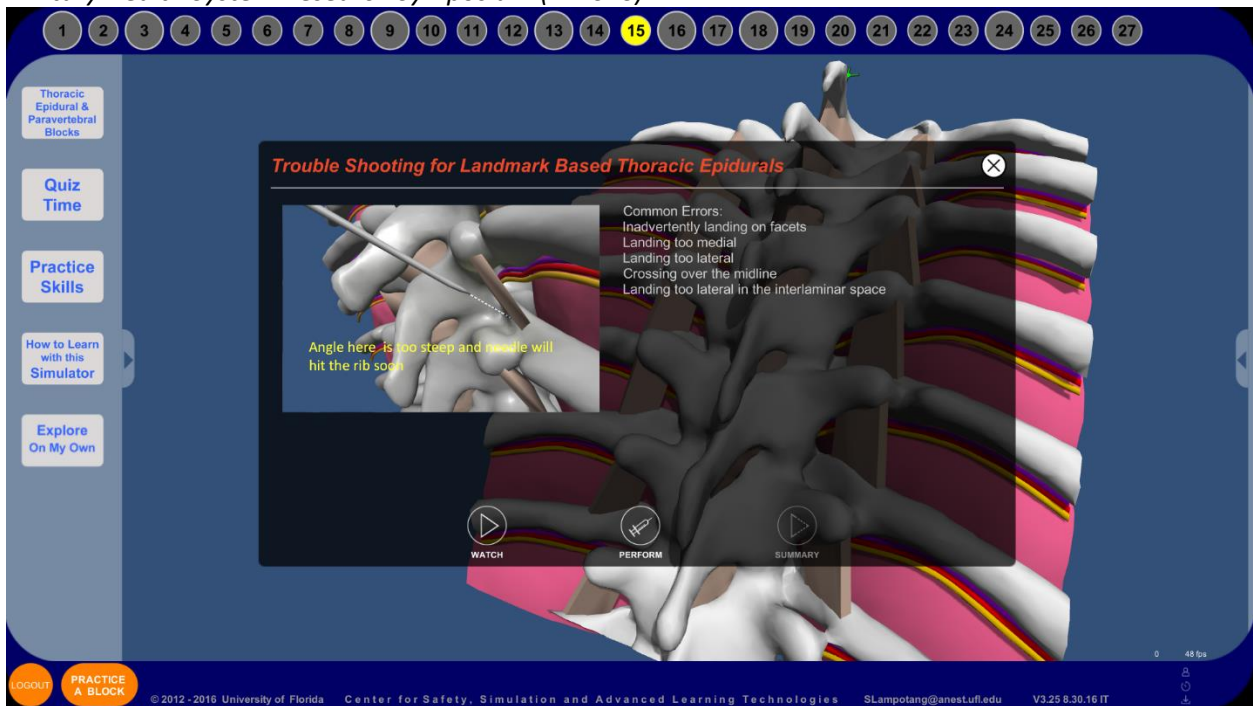
These three screenshots are of a skills exercise that focuses only on proper needle trajectory during Internal Jugular (IJ) Vein access

3. **Alignment Protocol:** We created an alignment protocol using hardware and software tools that improves and standardizes the way the SMARTS stand and tracked tools are registered to their tracking volumes and virtual models, respectively. We created a highly accurate 3D printed alignment block to fine tune our tracking volume, enabling a reduction of tracking error of our tracked tools to within 0.2 mm. The alignment block has cutouts that accepts SMARTS needles, ultrasound probes, and camera controllers to aid registration, measure registration drift, and provide quality control.
4. **Ventriculostomy Simulator Design and Dataset:** We prepared a library of 144 segmented brain scans from UF's Neuropsychology and Structural Neuro Imaging Laboratory for inclusion into the SMARTS virtual environment. We wrote a means for the SMARTS simulator to access a large external dataset. The 144 segmented brains have been normalized to fit either a standard male skull or a standard female skull. These two standard heads are being used to create physical models for the simulator. We modified a ventriculostomy scoring algorithm to match anatomical components available in the brain library's segmentation files. We also have a design concept for the ventriculostomy phantoms with scalp that can be rejuvenated (after being cut) and replaceable skull inserts after the skull has been drilled. We also have an alternate minimalistic design that does not require actual drilling.
5. **Improvements to the SMARTS platform design:** We created a standard user interface for using the SMARTS simulation in studies, including logging in, participant instructions, and changing hardware blocks. We redesigned the latch for SMARTS platform to remove/minimize vertical degree of freedom/displacement of the latch while maintaining lateral movement; result was a positive snap latch that works for all our users. We also improved anti-skid pads for the stands and simplified and slightly reduced the weight of the stands. The USB bus voltage on lightweight Surface tablets was causing microcontroller resets; we changed the power distribution design so that white box (electronics box) (see Figure 1) power brick provides power to the microcontroller instead of the Surface laptop.

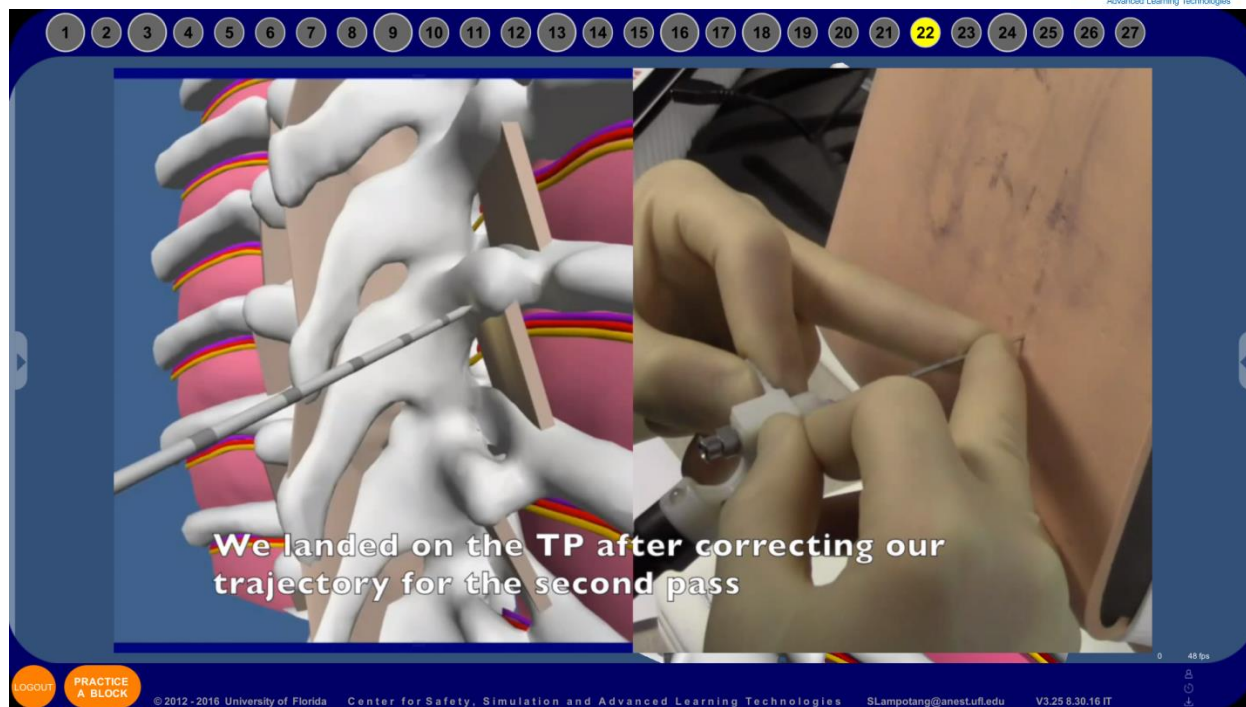
6. **Improvements to the RA simulator:** We reinforced the thoracic RA print with stronger ribs after clinical consult. We also added a dyed (flesh tone color) ballistic gel block for the RA simulator that does not need a skin flap to be placed over the gel block. We evaluated the needed frequency of rejuvenation of the color-dyed ballistic gel based on the amount of usage before the surface area becomes too porous to use without it affecting needle trajectory. Having only used skin flaps prior to cover the undyed gel blocks, we are simultaneously vetting the durability of the color-dyed ballistic gel while participants utilize the simulators. We adjusted the acceptable zone for ultrasound guided needle entry for the TPVB scoring algorithm for the RA study. After discussion with numerous clinicians, there was consensus that we were being too strict on what is considered an acceptable location for the completion of the TPVB block. The new, larger zone of acceptability is more accurate to what is clinically acceptable from our clinical consultations. We also improved the morphology of the superior costotransverse ligaments (SCTL) in the 3D anatomy for the RA simulator by making the SCTL thickness of tapered thickness instead of uniform thickness.
7. **Improvements to CVA Simulator:** We have created a plan to move toward a skinless, dyed CVA block that would be easier to rejuvenate. We also implemented venous collapse from pressure applied by the ultrasound probe and/or needle. The arteries in the simulated US image and in 3D visualization were modified to include pulsation according to heart rate in the CVA simulator.
8. **Improvements to CVA software:** Added syringe LED, “Needle in place” physical button, evaluation user interface, and pressure sensor calibration. We also made edits to CVA study video content for color-blind participants based on user feedback from a color-blind participant.
9. **Ultrasound simulation improvements:** The pressure sensors embedded in the simulated US probe face were calibrated to more accurately reflect the minimal required force applied through the US probe to collapse veins in the CVA simulator. Vein collapse as a result of realistic pressure applied via the US probe is simulated in both the US image and the 3D visualization. It was noted that some clinicians use their finger in order to determine the correct orientation of the ultrasound probe. They do this by placing it at one edge of the face of the ultrasound probe and seeing its resulting effect on the screen. The ultrasound was changed to allow the use of this finger artifact capability to let users utilize this method of determining ultrasound probe orientation.
10. We added a small pressure sensor to the syringe plunger valve to detect if the user is pulling or pushing on the syringe plunger. The CVA integrated tutor can use this information to score needle advancement technique and control simulated blood flashback (performed optically, not with liquids) in the syringe: if users do not apply proper traction on the syringe plunger when accessing the vein, they get no flashback of blood even though they have accessed the vein and consequently may continue their needle advancement, increasing the chance of backwalling and injury.
11. We built a third modular simulator platform for RA and CVA studies that will be conducted off-site.
12. We received a new small form factor modular CVA 3D print.

Year 2

1. **Integrated Tutor:** Based on preliminary, not yet published results from a completed learning outcome study on the CVA simulator, we developed in Year 2 an integrated tutor to facilitate self-study and self-debriefing with our SMARTS-compliant line of AR procedural simulators. The integrated tutor was first instantiated for the RA simulator. We developed software that inserts a variety of instructional materials into the simulation, including videos, simulation settings, screen captures of the 3D visualization, and optional custom programs for specialized learning objectives. Users can browse, watch instructional videos, and practice skills in any order. An abstract describing the integrated tutor for the RA simulator was submitted and accepted for presentation at the Military Health System Research Symposium (MHSRS).

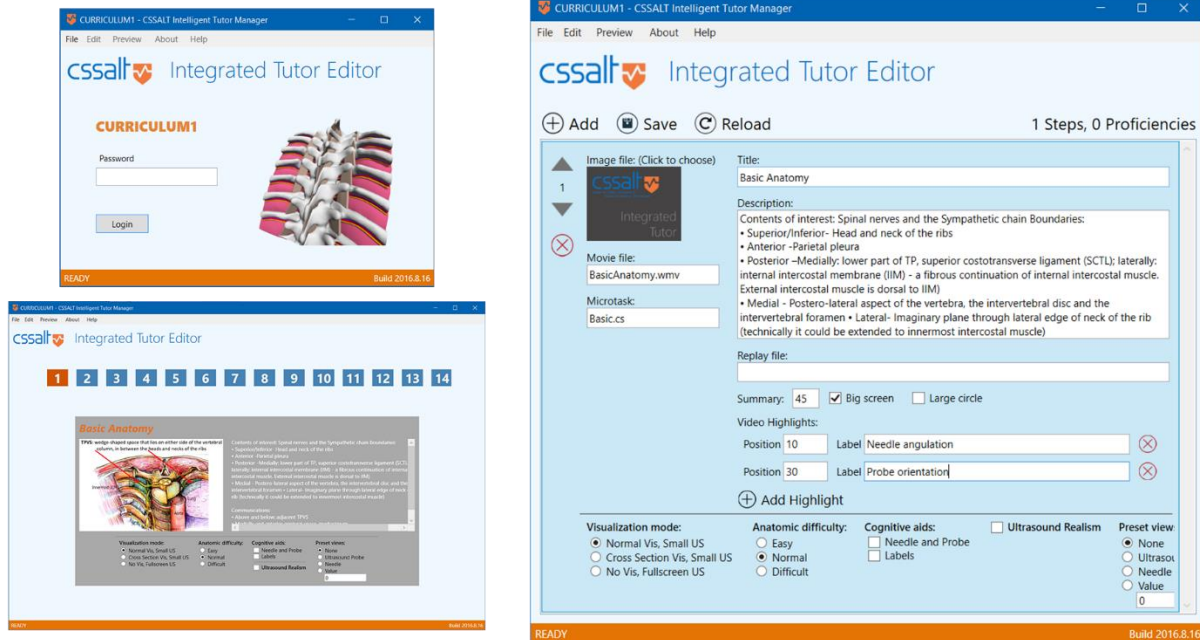


Screenshot of a menu from the integrated tutor for the RA simulator



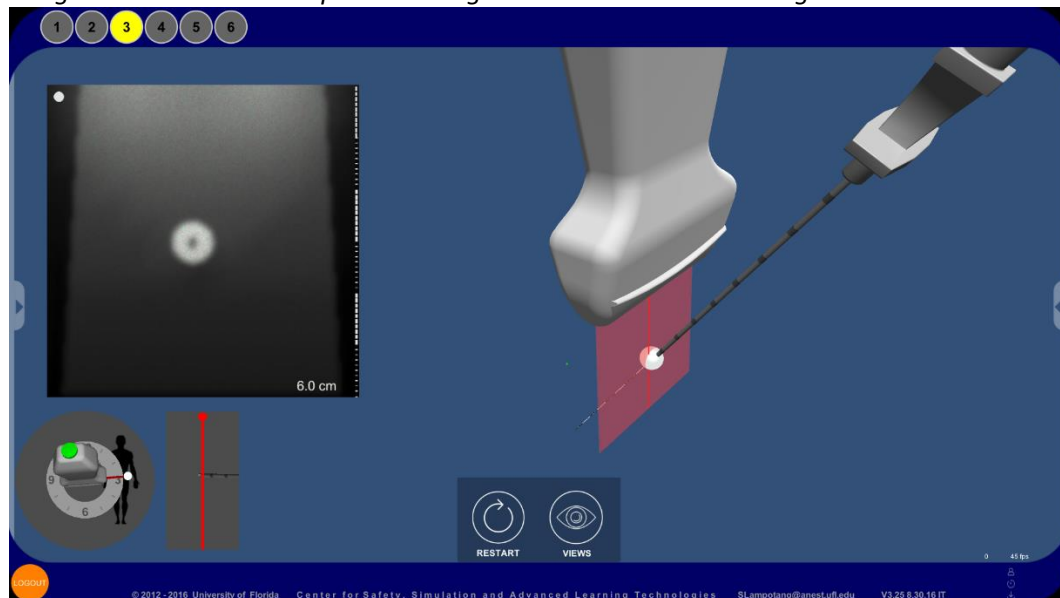
Split screen on integrated tutor for RA simulator: Left half: screenshot of display; Right half: screenshot of video playing for same procedure at exact same point in time

2. **Curricula:** Two detailed curricula for the RA simulator were developed for US-guided and US-assisted thoracic paravertebral blocks and US-assisted and landmark-based epidurals. This includes an hour of instructional videos; however, they are not presented all at once. Combined into one curriculum in the outcome study, they are split up into digestible sections or modules. The curricula are at <http://vam.anest.ufl.edu/rastudy2016/>
3. **Integrated Tutor Editor:** We realized we would need integrated tutors for all future AR simulators and created an integrated tutor editor to provide an environment to facilitate design and repurposing of existing integrated tutors for other procedures. We developed a way to enable clinicians, volunteers, non-developers (or anyone without programming background) to design and build intelligent tutor steps. The editor enables the clinical team to create and edit content that interacts with the AR simulators. First implemented for the RA simulator and being used in the ongoing learning outcome study (UF IRB02 Number 2014-U-0658. HRPO Log Number A-18036), the editor has been applied to design and implement an integrated tutor for the CVA simulator. An abstract describing the integrated tutor editor was submitted and accepted for presentation at the Military Health System Research Symposium (MHSRS).



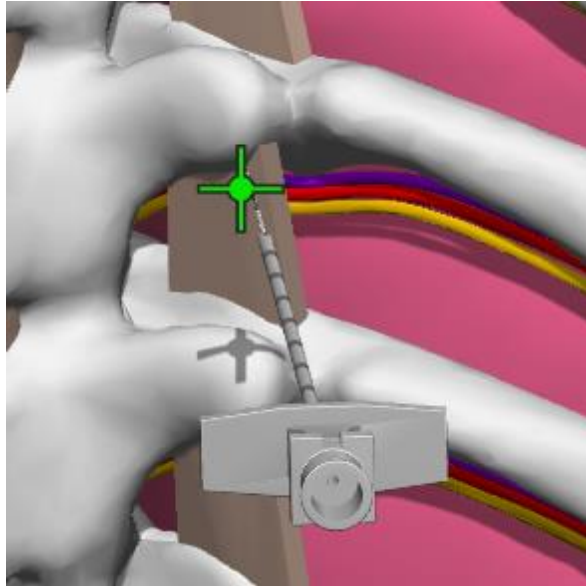
4. **Skill Scripts:** We created six self-contained exercises within the integrated tutor for the RA simulator that allow learners to temporarily pause the larger AR simulation and focus on practicing specific skills. The skill scripts are:

a. **Needling Target Exercise.** The virtual thoracic anatomy is removed and replaced with a small spherical target in the phantom. The user practices needling that target with any technique of ultrasound guidance or assistance. The location of the target is randomly changed by the integrated tutor. This is a procedure-agnostic drill because the target is non-anatomic.

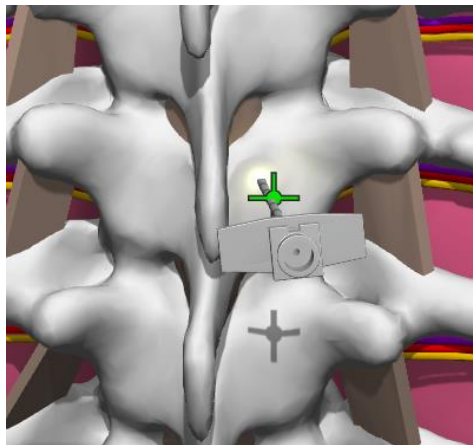


b. **Marking the skin puncture point for thoracic paravertebral blocks.** Learners set all else aside and focus on this important step of the curriculum. The learners' skin puncture point is

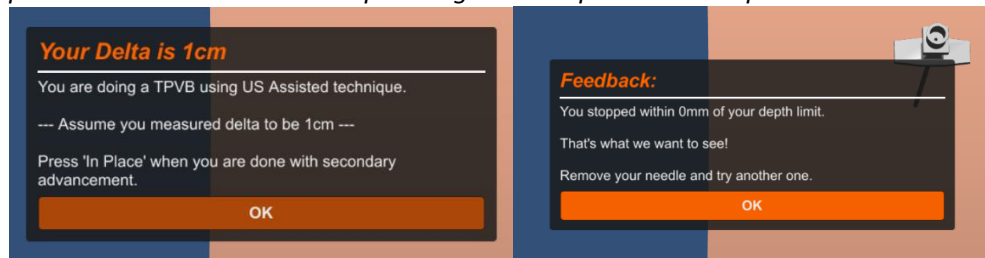
compared with the curriculum's ideal point. Side and level are specified and change each time. This is a procedure-agnostic drill because the target is only on the skin.



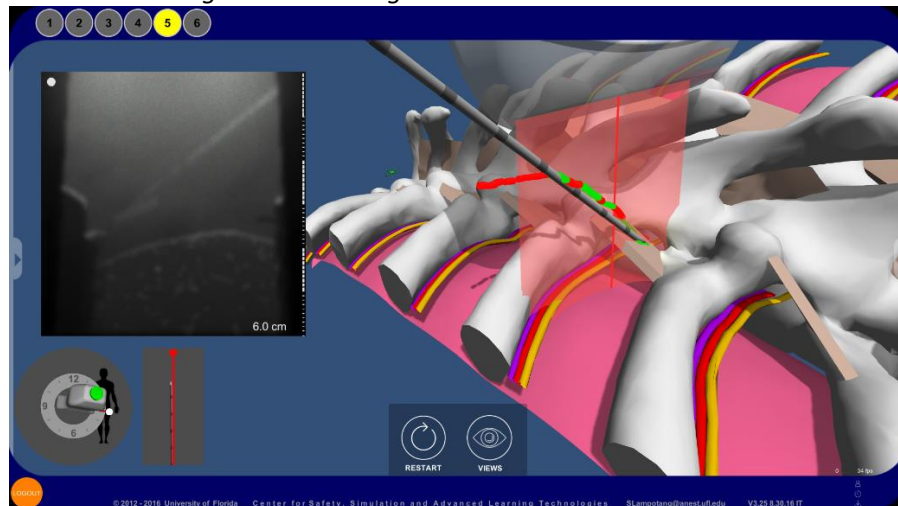
- c. Bone palpation exercise for thoracic epidurals. A skin puncture point is randomly specified by the integrated tutor and rendered on the virtual skin. It is not always at an ideal location. Users enter the skin at that specified point, palpate the bone with the needle, then compare their mental model with the 3D visualization, as shown below.



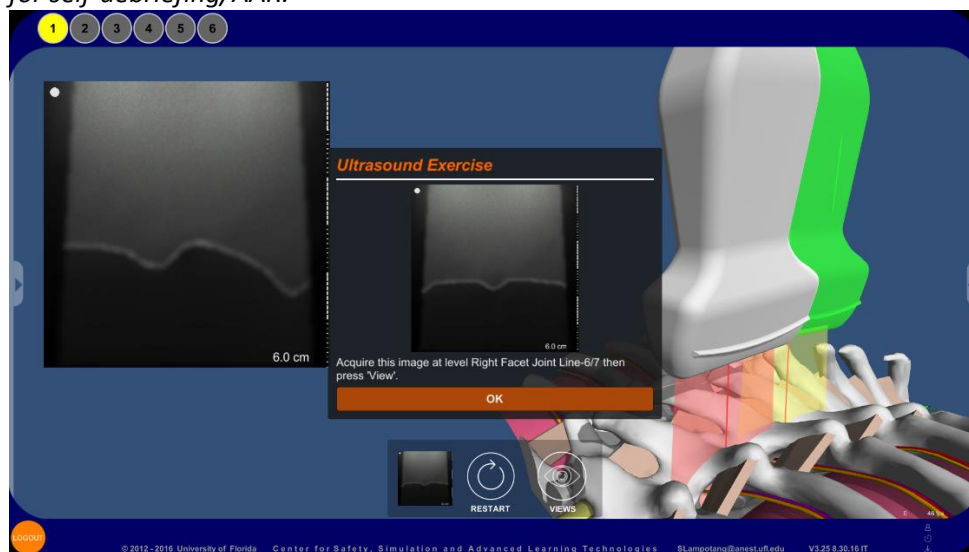
- d. Secondary Advancement. A skill specific for US-assisted thoracic paravertebral blocks: users practice needle advancement planning and discipline to avoid pneumothorax.



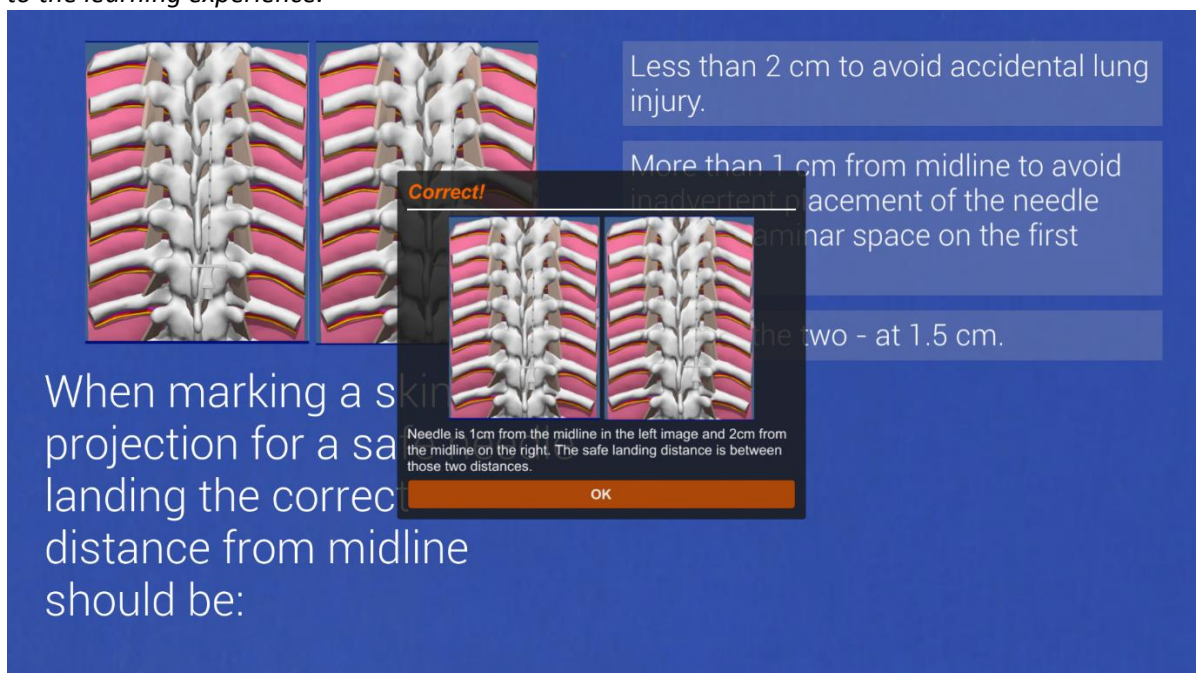
- e. In-plane needling skill: Users practice ultrasound-guided in-plane needling techniques. The needle path is color-coded for debriefing; green indicates that the needle tip is visible in the US image while advancing; red indicates the needle was advanced while the tip was not visible in US image. Procedure agnostic.



- f. Ultrasound image acquisition: Users are presented an ultrasound image and tasked with reproducing that image by correctly positioning their simulated ultrasound probe. The given images' probe position and the user's probe position are then superimposed and compared for self-debriefing/AAR.

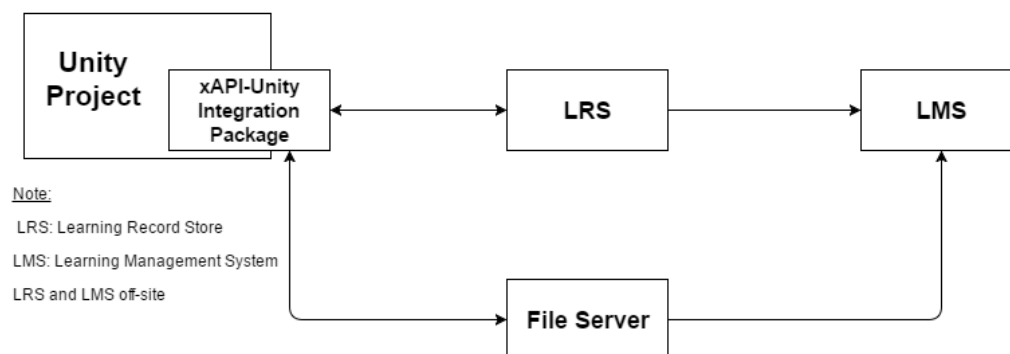


5. **In-simulation quiz:** a modular quiz element was added to the integrated tutor engine to add variety to the learning experience.



6. **Homework materials** common to all groups of the learning outcome study currently underway for the RA simulator are available at <http://vam.anest.ufl.edu/rastudy2016/>
7. **SCORM/xAPI Compatibility:** Based on interactions during the 2016 IPR at Ft. Detrick, the simulator output has been made xAPI-compliant so that its output will be compatible with an architecture such as the one below. We developed a software plug-in for our mixed reality software that can communicate with an xAPI-compatible learning record store (LRS) and learning management system (LMS). The plug-in has been tested, documented, and is ready to be installed.

xAPI-Unity Integration Package Flowchart



8. **Advanced Scoring Algorithm:** Specific scoring elements were added for US-assisted thoracic paravertebrals and epidurals, US-guided thoracic paravertebrals, and landmark-based epidurals. We

created an easy to read feedback element to the scoring algorithm which hides much of the details from the user.



The feedback/self-debriefing/after-action review screen generated by the automated scoring algorithm

```
20 practice minutes remain
40 practice blocks remain
3115 seconds viewing IT videos
5975 seconds practicing blocks
2425 seconds using replayer
1108 seconds practicing skills
8/15/2016 4:01:00 PM 240
8/16/2016 3:54:26 PM 161
8/19/2016 3:42:42 PM 89
8/19/2016 4:07:49 PM 64
8/22/2016 3:18:05 PM 72
8/22/2016 4:14:47 PM TestBlock3
8/22/2016 4:21:52 PM TestBlock4
8/22/2016 4:27:15 PM TestBlock1
8/22/2016 4:29:35 PM TestBlock2
8/22/2016 4:32:03 PM TestBlock6
8/22/2016 4:35:27 PM TestBlock5
```

Text log of a participant's progress through the curriculum

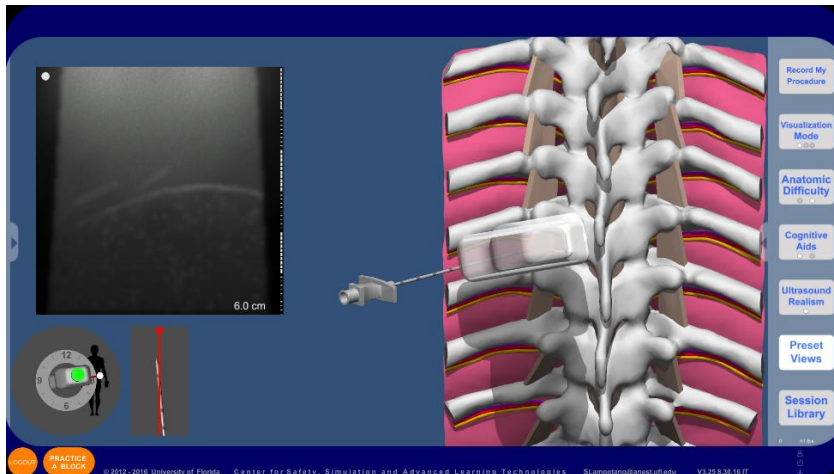
Participant	Group	Task	Technique	Procedure	Requested Side	Requested Level	Needle R	Penalty: E	Session Seconds	Ultrasound Used	Penalty: Ina	Penalty: Too Much Time	Bone Strikes	Penalty: To
Cx	C	TestBlock3	USAssisted	ThoracicParavertebral	Left	T5	Yes	0	386.5	yes	413.1	4	10	2
Cx	C	TestBlock4	USAssisted	ThoracicParavertebral	Right	T5	Yes	0	243	yes	126.1	8	50	5
Cx	C	TestBlock1	USGuided	ThoracicParavertebral	Left	T3	Yes	0	84.4	yes	0	0	0	1
Cx	C	TestBlock2	USGuided	ThoracicParavertebral	Right	T3	Yes	0	75.4	yes	0	0	0	1
Cx	C	TestBlock6	Landmark	Epidural	Mid	T6	Yes	0	148.9	no	28.9	1	0	2
Cx	C	TestBlock5	USAssisted	Epidural	Mid	T4	Yes	0	332	yes	304	16	550	2
Bz	B	TestBlock3	USAssisted	ThoracicParavertebral	Left	T7	Yes	0	39.8	yes	0	0	0	0
Bz	B	TestBlock1	USGuided	ThoracicParavertebral	Right	T5	Yes	0	122.4	yes	0	2.4	2	0
Bz	B	TestBlock2	USGuided	ThoracicParavertebral	Left	T6	Yes	0	136.3	yes	0	16.3	0	0
Bz	B	TestBlock4	USAssisted	ThoracicParavertebral	Right	T4	Yes	0	124.7	yes	0	4.7	4	10
Bz	B	TestBlock5	USAssisted	Epidural	Mid	T5	Yes	0	68.6	yes	0	0	5	0
Bz	B	TestBlock6	Landmark	Epidural	Mid	T6	Yes	0	33.3	no	0	0	3	0

Formatted spreadsheet output of ongoing study data (dynamically generated; truncated)

- We created and 3D printed a second modular test anatomy block that is an 85% scale, mirrored model of the practice anatomy module for the final exam stage of the RA simulator learning outcome study. The test block contains different anatomy and distances for the final exam, so that users are tested on a different, more difficult patient. For our study, we color-coded the blocks.



- We built a second modular simulator platform for the RA and CVA studies that will be conducted off-site.
- We **reformatted and downsized** the anatomic module for the CVA simulator so that it fits on the redesigned/enhanced modular stand. See Figure 2a
- Cognitive aids.** We added user-toggled (4th button from top on right column of buttons) cognitive aids to act as “training wheels” for novices. Two cognitive aids are displayed at the bottom left of the screen below. The left one shows a virtual probe and its orientation. The right one represents the alignment between the insonation plane (red line) and the needle (white line).



13. Created a **plug-in for the Ascension 3D Guidance system** for our simulation software suite
14. Designed and implemented a **SMARTS (System of Modular Augmented Reality Tracking Simulators) rapid development platform** with software plug-ins.
 - a. **Interoperable tracked tools.** As an example, the needle was re-designed to be application-agnostic and interchangeable between SMARTS-compliant simulators, irrespective of the application. The modular needle hub was also redesigned to be more robust with better registration and sensor protection.



- b. **Reduced simulator weight.** When packed in its mil spec case, our simulators now meet both size ($L + W + H \leq 60"$) and weight (≤ 50 lbs) restrictions for airline checked luggage.
- c. Redesigned hardware tracking box to be smaller, lighter, and quicker to assemble. New metal box below has better EMI noise shielding and is lighter than the previous Plexiglas box.



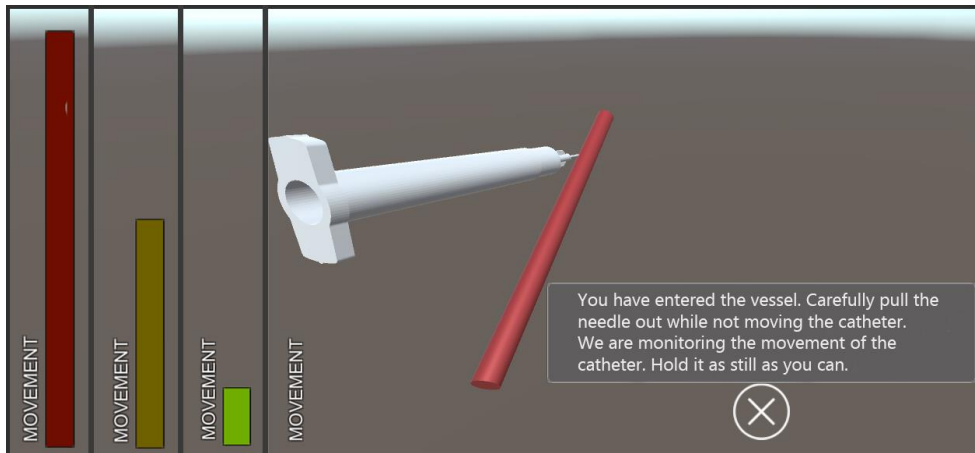
- d. **SMARTS modular stand upgrade:** we redesigned the modular stand to be made out of tough ABS plastic after mechanical failures of the previous leg design. The modular stand now is lighter and easier to make.



15. We refined the modular stand design to allow for more rotation and faster physical swapping (< 1 minute) of different anatomic modules by redesigning the quick release spring mechanism (white latch engaging in blue receptacle).



16. We reformatted and downsized the anatomic module for the CVA simulator module (see Figure 2a) so that it fits on the redesigned/enhanced SMARTS modular stand.
17. We developed, built and deployed an ultrasonography skills trainer
18. We developed and built a proof of concept IV line insertion trainer



19. **Upgraded tracking system** to work with a smaller, lighter tracking transmitter that is also more accurate. Developed in-house signal filters that allow needle tracking sensors to work with the smaller transmitter. Upgraded firmware to work with the custom filters.
20. **Upgraded electromagnetic interference shielding** was added to the needle, tracked camera, simulated ultrasound probe, microcontroller assembly, and tracking hardware box. The shielded cables are also easier to assemble.
21. Designed a microcontroller printed circuit board for faster manufacturing and outsourcing.
22. Changed the connectors from the tracked tools to the microcontroller to an industry standard: 3mm 8 position Micro MATE-N-LOK AMP connector made by TE Connectivity

Opportunities Provided for Training and Professional Development

Year 3 (8/1/2016-7/31/2017)

The Phase I mixed simulators were demonstrated and/or used during Year 3 of grant W81XWH-14-1-0113 per table below.

Institution / Event	Location	Simulators •RA = Regional Anesthesia •CVA = Central Venous Access •UST = Ultrasonography •SMARTS Platform	Dates	Number of trainees	Point of Contact/ Clinician
Vanderbilt Loan	Nashville, TN	RA	9/1/16-9/15/16	~ 7 residents trained	David Allan Edwards, MD, PhD
UCLA CRESST (National Center for Research on Evaluation, Standards, and Student Testing)	Los Angeles, CA	UST and SMARTS	9/20/16	~ 6	S. Lampotang, PhD
NYSORA	New York, NY	RA	9/23/16-9/25/16	~ 25	Barys Ihnatsenka, MD
NAVat (Automated Low Flow Anesthesia & Visual Drug Display Systems) Hands-on demo	Alast, Belgium	RA, CVA, UST, and SMARTS	9/24/16	~ 10 (6 Medical Students, 4 Anesthesia residents)	S. Lampotang, PhD
Universitair Ziekenhuis Antwerpen (UZA) Hands-on demo	Antwerp, Belgium	UST and SMARTS	9/27/16	~ 25 (3 faculty, 22 anesthesia residents)	S. Lampotang, PhD
CSSALT Open House presentation of simulation	Gainesville, FL	UST and SMARTS	10/4/16	~ 20	S. Lampotang, PhD D. Lizdas, BSME
UF Student CVA Presentation	Gainesville, FL	CVA	10/12/16	~ 25	C. Giordano, MD
UF College of Medicine Alumni Homecoming presentation	Gainesville, FL	UST and SMARTS	10/15/16	~ 30	S. Lampotang, PhD
USSA/AVAA (Uniformed Services Society of Anesthesiologists) neuraxial blocks workshop	Chicago, IL	RA and UST	10/21/16	~ 35	Cdr. Michael Kent, MD, USN Anesthesiologist
ASA – 813 -Ultrasound Guided Advanced Blocks	Chicago, IL	RA	10/22/16	~ 50	B. Ihnatsenka, MD, L. Le-Wendling, MD, Y. Zasimovich, MD
ASA – 848 - Advanced Technology Workshop	Chicago, IL	RA	10/22/16	~ 7	S. Lampotang, PhD D. Lizdas, BSME
ASA – 839A -Peripheral Nerve Blocks: Ultrasound, Simulation and Stimulation; MOCA endorsed	Chicago, IL	RA	10/24/16	~ 21	B. Ihnatsenka, MD L. Le-Wendling, MD
ASA – 839B – Peripheral Nerve	Chicago, IL	RA	10/25/16	~ 26	B. Ihnatsenka, MD

Blocks: Ultrasound, Simulation, and Stimulation; AM Workshop					L. Le-Wendling, MD
ASA – 839C – Peripheral Nerve Blocks: Ultrasound, Simulation, and Stimulation; PM Workshop	Chicago, IL	RA	10/25/16	~ 7	L. Le-Wendling, MD
Northwestern University Demo	Evanston, IL	RA, CVA, UST, and SMARTS	10/26/16	~ 10 (4 faculty, 6 residents)	S. Lampotang, PhD
Northwestern University Loan	Evanston, IL	RA & CVA	10/27/16 - 11/22/16	~ 5 anesthesiologists	L. Wade, MS
CSSALT Open House presentation of simulation	Gainesville, FL	UST and SMARTS	11/3/16	~ 20	S. Lampotang, PhD, D. Lizdas, BSME, T. Johnson, BS, A. DeStephens, MSME
MOCA Hands-On Demonstration	Gainesville, FL	RA, CVA, UST, and SMARTS	11/5/16	~ 8 anesthesiologists	S. Lampotang, PhD, N. Gravenstein, MD, C. Giordano, MD
CVA Workshop	Gainesville, FL	CVA	11/9/16 - 11/17/16	~ 20 anesthesia interns	J. Sappenfield, MD
Cleveland Clinic Conference – Cadaveric Regional Anesthesia Ultrasound Workshop	Cleveland, OH	RA	12/3/16	~ 50	B. Ihnatsenka, MD
CSSALT Open House simulator demo	Gainesville, FL	RA, CVA, UST, and SMARTS	12/8/16	~ 14	S. Lampotang, PhD T. Johnson, MSME
Fort Sam Houston Resident Training Day	San Antonio, TX	RA, CVA	12/16/16	~ 30	B. Fitzgerald, MD, Lt. Col (USAF)
IMSH (International Meeting on Simulation in Healthcare) Exhibit/Demo	Orlando, FL	RA, CVA, UST, and SMARTS	1/28/17 - 1/31/17	~ 85	S. Lampotang, PhD D. Lizdas, BSME T. Johnson, MSME
Sick Kids Sim Loan	Toronto, Canada	RA	2/2/17-3/13/17	~ 12	T. Everett, MBChB
Sick Kids Presentation AM Session	Toronto, Canada	RA, CVA	2/8/17	~ 28 (10 faculty, 18 trainees)	S. Lampotang, PhD
Sick Kids Presentation PM Session	Toronto, Canada	RA, CVA	2/8/17	~ 20 (12 faculty, 8 trainees)	S. Lampotang, PhD
John Hopkins School of Medicine Demonstration	Baltimore, MD	RA	2/22/17	~ 6	P. Tighe, MD, MS
University of MD; Medical School Teaching Facility Demonstration 1	College Park, MD	RA	2/24/17	~ 40	P. Tighe, MD, MS Y. Zasimovich, MD
University of MD; Medical School	College Park,	RA	2/25/17	~ 56	P. Tighe, MD, MS

Teaching Facility Demonstration 2	MD				Y. Zasimovich, MD
CSSALT Demo for Dr. James Murray Royal College of Surgeons Ireland, UF COM Dean Mike Good	Gainesville, FL	RA, CVA, UST, and SMARTS	3/3/17	~ 2	S. Lampotang, PhD D. Lizdas, BSME
Catherine Price Laboratory Demo	Gainesville, FL	UST and SMARTS	3/10/17	~ 10	S. Lampotang, PhD T. Johnson, MSME
NYSORA – Advanced Blocks: Thoracic/Paravertebral/Intercostal/Epidural/Caudal workshop	Dubai, UAE	RA, CVA, and UST	3/23/17	~ 30	B. Ihnatsenka, MD
NYSORA – Blocks for knee surgery workshop	Dubai, UAE	RA, CVA, and UST	3/24/17	~ 30	B. Ihnatsenka, MD
NYSORA – Gastric, lung, airway, ultrasound, transcranial, & abdomen workshop	Dubai, UAE	RA, CVA, and UST	3/25/17	~ 30	B. Ihnatsenka, MD
CSSALT Open House Demo	Gainesville, FL	UST	3/30/17	~ 13	S. Lampotang, PhD T. Johnson, MSME
Dental Students Demo	Gainesville, FL	UST	4/4/17	~ 3	S. Lampotang, PhD D. Lizdas, BSME
ASRA Presentation	San Francisco, CA	RA	4/4/17	~ 30	B. Ihnatsenka, MD
ASRA Workshop	San Francisco, CA	RA	4/7/17	~30	B. Ihnatsenka, MD
Simulator Demo for Interviewing Fellowship Students	Gainesville, FL	RA	4/8/17	~ 8 (Potential fellows)	L. Le-Wendling, MD
Cross-Sectional Literacy as a Foundation for Ultrasonography – Friday Morning Simulation Conference	Gainesville, FL	UST	4/14/17	~ 22	S. Lampotang, PhD
7 th Annual Cadaver and Ultrasound Workshop Regional Anesthesia and Point of Care Ultrasound at UPENN	Philadelphia, PA	RA	4/21/17	~ 35	Y. Zasimovich, MD
Northeast Florida Association for Medical Instrumentation (NEFAMI) Florida Biomedical Society	Gainesville, FL	UST	4/26/17	~ 25	S. Lampotang, PhD
Mixed Reality Simulator For Teaching Learning Thoracic RA	Chengdu, Sichuan Province, China	RA, CVA, and UST	5/10/17 – 5/22/17	~ 50	B. Ihnatsenka, MD
3 Thoracic Regional Anesthesia Workshops “Technical Aspects of Placing Thoracic Epidural”	Chengdu, Sichuan Province, China	RA	5/10/17 – 5/22/17	~ 60	B. Ihnatsenka, MD
"Teaching Complex Skills in Anesthesia Residency with Focus on Thoracic Epidurals and Thoracic Paravertebral Blocks" University of Wisconsin Department of	Madison, WI	RA	7/18/17-Present	~50	B. Ihnatsenka, MD

Anesthesiology Grand Rounds					
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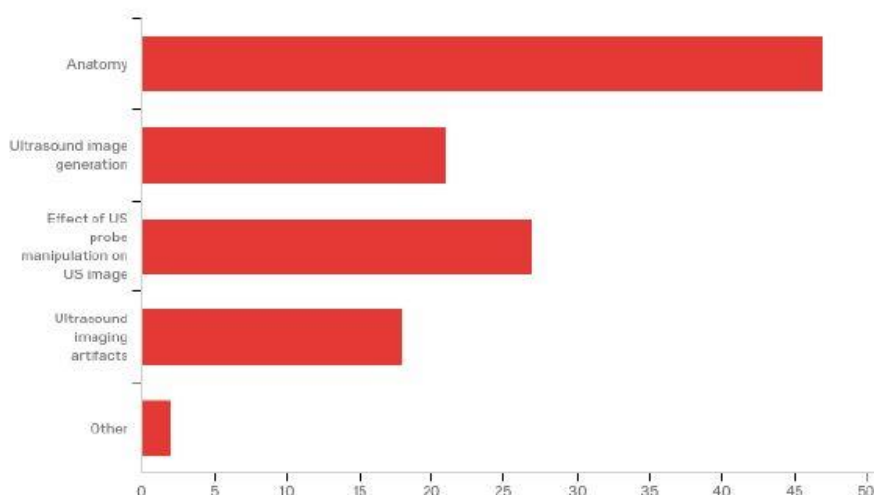
Examples of the feedback received from the external evaluation sites via an online Qualtrics survey tool at https://ufl.qualtrics.com/SE/?SID=SV_8uLi3fda221ayR7 are below.

Q16 - Experience with this simulator would be useful for novices and practicing clinicians.

#	Answer	%	Count
1	Strongly disagree	0.00%	0
2	Disagree	0.00%	0
3	Somewhat disagree	0.00%	0
4	Neither agree nor disagree	0.00%	0
5	Somewhat agree	9.62%	5
6	Agree	28.85%	15
7	Strongly agree	61.54%	32
	Total	100%	52

Q19 - Experience

with the simulator training improved my understanding of:



#	Answer	%	Count
1	Anatomy	40.87%	47
2	Ultrasound image generation	18.26%	21
3	Effect of US probe manipulation on US image	23.48%	27
4	Ultrasound imaging artifacts	15.65%	18
5	Other	1.74%	2
	Total	100%	115

Year 2 (8/1/2015-7/31/2016)

The Phase I thoracic Regional Anesthesia (RA) mixed reality simulator was used during Year 2 of the grant W81XWH-14-1-0113 at the University of Florida on several different occasions including the inauguration of UF's new president Fuchs. It was also used at multiple military institutions and sites such as Veterans Health Administration SimLearn Simulation Center (Oct. 2015), Naval Medical Center San Diego (10/26/15-12/14/15), Veterans Administration SimLEARN (11/24/15), Fort Detrick (3/29/16), Walter Reed National Military Medical Center (4/15/16-5/2/16), Brooke Army Medical Center (4/19/16-6/10/16), and the Wilford Hall Ambulatory Surgical Center (5/1/16). The RA simulator was also utilized at the Stanford Medicine X Ed Meeting in a simulator design workshop with 30 trainees. Dr. Ihnatsenka presented the RA as well at the Moffitt Cancer Center, ASA's annual meeting as well as a regional anesthesia workshop at ASA. A second visit to GatorRAP a year later was performed as well as the University of Southern California by Dr. Lampotang.

Our CVA simulator was utilized at multiple events throughout the year including the previously mentioned Stanford Medicine X Ed Meeting, Veterans Health Administration SimLEARN Simulation Center, Veterans Administration SimLEARN, UF's inauguration of President Fuchs, the University of Southern California, GatorRAP, Fort Detrick, Brooke Army Medical Center, Wilford Hall Ambulatory Surgical Center, Villanova University, Veterans Affairs Medical Center, and the First Maternal and Infant

Hospital. The CVA simulator (along with the RA and ultrasonography skills simulator) were also presented at the Association of Anesthesiologists of Mauritius by Dr. Lampotang on 7/21/16 and 7/28/16.

Year 1 (8/1/2014-7/31/2015)

The Phase I Thoracic Regional Anesthesia (RA) mixed simulator was used during Year 1 of grant W81XWH-14-1-0113 at the University of Florida (UF) (approximately on 5 occasions) and the Massachusetts General Hospital (three times: 5/12-17/2014; 2/4/15; 5/20/15) for resident and faculty training. It was also extensively demonstrated as a compact, transportable, turnkey system at the World Congress of Regional Anesthesia and Pain Therapy (WCRAPT, Cape Town, South Africa, November 23-28, 2014), in the Government Corral at the International Meeting on Simulation in Healthcare (IMSH, New Orleans, LA, January 11-13, 2015), 3rd Annual Acute Pain Medicine & Regional Anesthesia Conference (Baltimore, MD, February 14-15, 2015) and GatorRAP (Gainesville, FL, February 21, 2015) meetings. The GatorRAP 2-day workshop focuses on regional anesthesia techniques and makes use of cadavers, live animal models, live human models and part task trainers including our simulators; the audience includes practitioners of regional anesthesia for human and veterinary medicine. Our simulators (2 RA simulators and one cross-sectional literacy trainer) were well received by both audiences. During WCRAPT, our RA simulator was also used extensively (3 days) at the University of Stellenbosch Tygerberg campus for hands-on workshops and also at the Cape Town International Convention Centre.

Our CVA simulator was used with IRB 02 approval (2013-U-1025) and informed consent by 76 study participants at the University of Florida allowing them to become more familiar with the relevant anatomy, strategy, techniques and approaches for CVA as well as the physics and anomalies of ultrasound imaging. The breakdown of the 76 participants trained in Central Venous Access via our CVA simulator is as follows:

- 6 Anesthesia Faculty members
- 1 Anesthesia Attending
- 14 Interns/PGY1 (Post Graduate Year 1)
- 10 CA1/PGY2 (Clinical Anesthesia Year 1/ Post Graduate Year 2)
- 16 CA2/PGY3 (Clinical Anesthesia Year 2/ Post Graduate Year 3)
- 13 CA3/PGY4 (Clinical Anesthesia Year 3/ Post Graduate Year 4)
- 7 Fellows/PGY5 (Post Graduate Year 5)
- 6 CRNAs (Certified Registered Nurse Anesthetists)
- 3 Medical Students

Dissemination to Communities of Interest

Year 3 (8/1/2016-7/31/2017)

Our turnkey simulators were loaned for evaluation for extended periods of time to:

- Vanderbilt University, Nashville, TN
- Northwestern University, Evanston, IL
- Sick Kids Hospital, Toronto, Canada

The RA simulator based multiple choice questions (MCQ) Qualtrics quizzes that are used for performing the Thoracic ParaVertebral Block (TPVB) have been updated to reflect the current curriculum. The online quizzes were updated and separated by the technique being used into four separate styles of placements.

MCQ Test for Block 1 – Ultra Sound Assisted TPVB

(https://ufl.qualtrics.com/jfe/form/SV_aXLqzSRXvVmqs1n)

MCQ Test for Block 2 – Ultra Sound Guided TPVB

(https://ufl.qualtrics.com/jfe/form/SV_byMZE69QaWyKtcf)

MCQ Test for Block 3 – Landmark Based Epidural

(https://ufl.qualtrics.com/jfe/form/SV_eJmTEUeeryQVox)

MCQ Test for Block 4 – Thoracic Epidural & Ultra Sound Assisted Epidural

(https://ufl.qualtrics.com/jfe/form/SV_ehPgoRttamDjbKd)

Year 2 (8/1/2015-7/31/2016)

Our turnkey simulators were loaned for evaluation for extended periods of time to:

- Naval Medical Center, San Diego, CA
- Walter Reed National Military Medical Center, Bethesda, MD
- Brooke Army Medical Center, San Antonio, TX
- Wilmington Delaware Veterans Affairs Medical Center, Wilmington, DE

An RA-simulator based Qualtrics quiz on performing the Thoracic ParaVertebral Block (TPVB) was placed online on March 15th, 2016. This online quiz has been used by clinicians and trainees at the four military sites that beta tested our simulators.

MCQ Test for TPVB Curricula 1 and 2:

(http://survey.az1.qualtrics.com/SE/?SID=SV_0vVfq13RsvPSW1L)

A manuscript is in the final stages before submission for peer review by the journal Anesthesia & Analgesia. The manuscript describes a learning outcome study conducted on the CVA simulator on supraclavicular access to the subclavian vein – see flowchart of study protocol below. Augmentation of the simulator via 3D, color-coded, real-time visualization did not appear to make a difference in performance and seem to indicate that there is a need for instruction and a curriculum and/or that the supraclavicular approach is so straightforward that the visualization makes no difference. These learning outcomes have motivated us to explore integrated tutors for our AR simulators. Preliminary data that are excerpted from the manuscript are included below.

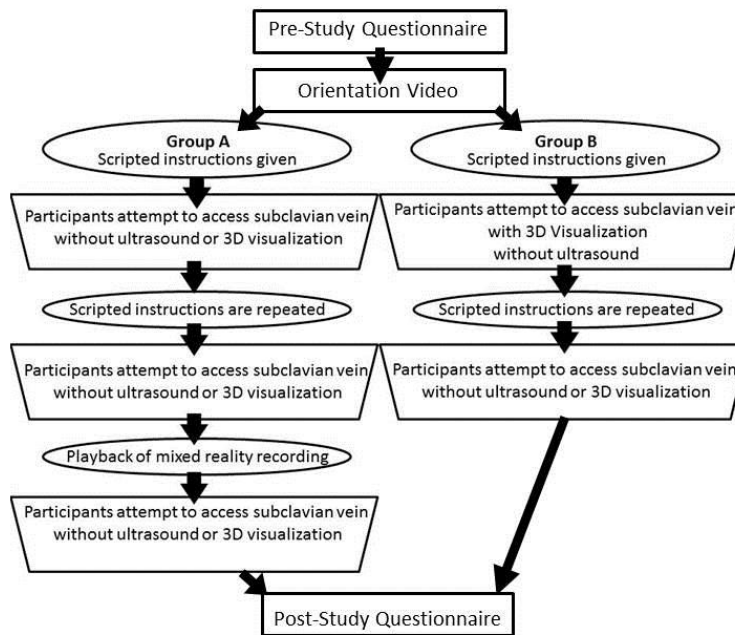


Table 1. Descriptive statistics for the supraclavicular approach experimental groups (with 3D visualization and without). Values are scores generated by an automated scoring algorithm.

Trial	No Visualization (n = 42)				Visualization (n = 27)			
	M	SD	95% CI	Mdn	M	SD	Lower 95%	Mdn
Baseline	533.1	108.8	(499.2, 567.0)	565.6	577.7	16.6	(571.2, 584.3)	584.8
Final Trial	568.7	42.1	(555.5, 581.8)	584.1	576.4	42.7	(559.5, 593.2)	590.2

Table 2. Complications and scoring penalties prior to simulator-based training (Baseline) and after simulator-based training (Post-Intervention)

Trial	Backwall Errors	Pneumothorax	Arterial Puncture
Baseline	8	3	1
Post-Intervention	4	1	0

Table 3. Errors, Penalties and Complications by Approach (N=69)

	Supraclavicular			Internal Jugular (IJ)			Infraclavicular (SC)		
	Visualization	No visualization	Total	Visualization	No visualization	Total	Visualization	No visualization	Total
Backwall									
Baseline	1	7	8	6	10	16	8	3	11
Post-intervention	1	3	4	5	4	9	2	2	4
Pneumothorax									
Baseline	0	3	3	1	0	1	2	4	6
Post-intervention	0	1	1	0	0	0	1	1	2
Arterial Puncture									
Baseline	0	1	1	1	5	6	0	1	1
Post-intervention	0	0	0	2	1	3	0	1	1
Extra Attempts									
Baseline	0	3	3	2	3	5	21	17	38
Post-intervention	1	0	1	0	1	1	14	6	20

A second manuscript describing results from a learning outcome study of our CVA simulator for the IJ and infraclavicular approaches to the subclavian vein is in a more preliminary state and will be submitted for peer-reviewed publication in year 3.

Our simulators are an integral part of demonstrations we conduct on a regular basis for our simulation center visitors that include high school students, STEM programs and science programs for high school students, programs for minority and under-represented students, medical school applicants, residency program applicants, visiting professors, medical industry executives and engineers and educators including high school science teachers.

Year 1 (8/1/2014-7/31/2015)

Results were disseminated via the demonstrations, meetings and workshops described above. In addition, the simulators are an integral part of demonstrations we conduct on a regular basis for our simulation center visitors that include high school students, STEM programs and science programs for high school students, programs for minority and under-represented students, medical school applicants, residency program applicants, visiting professors, medical industry executives and engineers and educators including high school science teachers.

*In addition, the real-time, 3D, color visual augmentation in our RA simulator helped a local RA and thoracic paravertebral block (TPVB) SME invent a new technique for TPVB: the Sagittal Paramedian (SP) Oblique (SP-Oblique TPVB). This innovative development (and possibly a first) of a simulator helping to invent a new technique that is efficacious on patients was submitted on 3/6/15 to the journal *Simulation in Healthcare* for peer-reviewed publication as an Empirical Investigation paper. The paper received generally positive reviews; the editor has suggested splitting the paper (which did contain a lot of information) into three peer-reviewed publications.*

Plan for Next Reporting Period to Meet Goals & Objectives

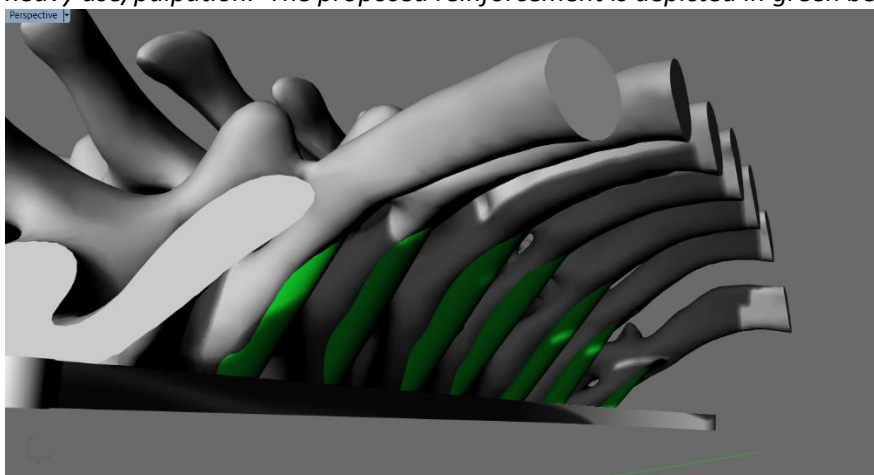
Year 3

- We will finalize the ventric (EVD) simulator design and build a SMARTS-compliant ventric simulator using the SMARTS SDK.
- We complete the learning outcome study on the SMARTS CVA simulator

- We will finalize the needs assessment document for the TRUS prostate biopsy simulator
- We will start designing the TRUS prostate biopsy simulator
- We will finalize the needs assessment document for the chest tube insertion (CTI) simulator
- We will start designing the chest tube insertion (CTI) simulator

Year 2

- *We will finalize the patient outcomes study. We plan to submit another IRB01 (prospective instead of retrospective) application in year 3 in preparation for the patient outcomes study. Our goal is to obtain IRB01 approval by December 2016 so that we can start collecting and doing preliminary analyses on pre-intervention (retrospective) patient and complication data related to CVA.*
- *We plan to complete the needs assessment for the EVD, prostate biopsy and chest tube insertion simulator in 2017.*
- *We will start to design the transfer of practice and ROI outcomes studies.*
- *We will redesign the CVA modular anatomy to be lighter and stronger. We will change the material to 3D printed nylon. Our first modular CVA anatomy was found to have inadequate tissue feel; currently undergoing design modifications to include better tactile landmarks and reduced give over the puncturable skin area.*
- *We will reinforce the cantilevered ribs on the RA simulator as some ribs have broken during heavy use/palpation. The proposed reinforcement is depicted in green below the ribs.*



- *We will repurpose elements of the RA simulator such as integrated tutor, procedure agnostic mini-skills, and in-program quiz for the CVA outcome study*
- *We will design and submit a learning outcome study to UF IRB 02 and HRPO for a prospective study of the reduced/modular format CVA simulator.*

IMPACT:

Year 3 (8/1/2016-7/31/2017)

Preliminary data from our CVA learning outcome study indicate that an integrated tutor may be non-inferior to an average human instructor. If this result is confirmed when more participants have performed the study, this will be a paradigm shift in simulator design and use, by demonstrating that self-study and self-debriefing are feasible and efficacious for simulator-based training, thereby also facilitating competency-based, instead of traditional time-based, training.

A manuscript describing a study that indicated that visual augmentation (3D real time visualization), whether real-time or delayed, increases performance has been accepted pending minor revision by the journal *Anesthesia & Analgesia*.

The development of an SDK will allow additional simulators beyond the 5 simulators scheduled for delivery to DoD to be developed by third parties.

Year 2 (8/1/2015-7/31/2016)

The results from our learning outcome study using the CVA simulator indicate that the supraclavicular approach to the subclavian vein may be an inherently safe approach (see Table 3) to use for central venous access that is not used as frequently as it might be indicated because most clinicians are unfamiliar with the technique. The CVA simulator could be a tool to provide military and civilian clinicians exposure and familiarity with supraclavicular access to the subclavian vein. Our unexpected results seem to be consistent with two peer-reviewed papers:

- Czarnek T. et al: *Supraclavicular Approach Is an Easy and Safe Method of Subclavian Vein Catheterization Even in Mechanically Ventilated Patients: Analysis of 370 Attempts.* *Anesthesiology* 2009; 111:334–9
- Shannon P. et al: *Supraclavicular Subclavian Vein Catheterization: The Forgotten Central Line.* *Western Journal of Emergency Medicine* 2009, 10(2); <http://escholarship.org/uc/item/8kf7q46w>

Year 1 (8/1/2014-7/31/2015)

The modularity of the modular stand allowed us to readily implement a cross-sectional literacy trainer that was exhibited together with our RA and CVA simulators at the Government Corral at IMSH in New Orleans, LA from January 11 to 13, 2015. The cross-sectional trainer has been extremely well received by practicing clinicians and medical and physician assistant students alike. It has sensitized medical educators and instructors to the fact that the fundamentals of cross-sectional literacy have been shortchanged, if addressed at all, in most healthcare curricula. Cross-sectional literacy underpins the ability of clinicians to interpret imaging modalities such as ultrasound imaging that produce 2D cross-sections out of 3D objects and to use ultrasound guidance to safely steer needles to their intended targets. The cross-sectional literacy trainer is intentionally devoid of anatomy and is thus procedure-agnostic. It will be applicable to all medical and healthcare disciplines where medical imaging that produces 2D cross-sections (such as ultrasound imaging) are produced. While the cross-sectional literacy and ultrasonography skills trainer is a spin-off of our DoD research and facilitated by the availability of the modular stand, we are not sure whether we need to continue reporting on this technology/application in future reports as part of the DoD grant, since our formal request to swap the cross-sectional literacy trainer for the chest tube insertion trainer was denied. See http://simulation.health.ufl.edu/research/US_Trainer_Demo_Video.wmv.

The real-time, 3D, color visual augmentation in our RA simulator helped our regional anesthesia SME invent a new technique for thoracic paravertebral block (TPVB): the Sagittal Paramedian (SP) Oblique (SP-Oblique TPVB). This technique developed via an anatomically correct simulator with visual augmentation has been tried on patients and found to be efficacious.

CHANGES/PROBLEMS:

Year 3 (8/1/2016-7/31/2017)

Scoring Algorithm Changes on CVA study: We added in Long Axis / Short Axis ultrasound probe detection and also added an In-Plane scoring monitor.

Year 2 (8/1/2015-7/31/2016)

No substantial changes were made.

We were instructed to not acknowledge DoD support for DoD-funded work (post-intervention data processing and statistical analysis and manuscript preparation) for 2 manuscripts we are submitting for publication because the study data was collected prior to the official start of the DoD grant (8/1/2014) with UF IRB02, but therefore not HRPO, approval.

Year 1 (8/1/2014-7/31/2015)

Change of Deliverable (approved by DoD on 4/22/15)

We made a formal written request to replace the proposed Focused Assessment with Sonography of Trauma (FAST) trainer in the original proposal with a mixed reality simulator for TransRectal UltraSound (TRUS)-imaged, manually-guided needle biopsy of the prostate. This request was made because the accuracy and uniform distribution of sampling during TRUS-imaged, manually-guided prostate needle biopsy trainer is poor, an undesirable state of current practice that is particularly relevant to the aging male population in the VA Health system and therefore to the DoD and also for the aging general male civilian population at large. Our request to replace the FAST trainer with the prostate biopsy trainer received approval via an email from Mr. Meinberg on 4/22/15.

While the change to a prostate biopsy simulator will most impact Phase II deliverables to DoD, it will also impact Phase I deliverables because, as a result, we will, in Phase I, conduct needs assessment for the prostate biopsy trainer, not for the FAST trainer.

PRODUCTS:

Year 3 (8/1/2016-7/31/2017)

Number of peer-reviewed publications (include ones that are pending publication):

MHSRS Abstract: 3

ASA Abstract: 1

UF College of Medicine Celebration of Research: 1

UF Dept. of Anesthesiology Celebration of Research: 3

IMSH 2017 Abstract: 1

- *“Visualization Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator” manuscript accepted for publication pending minor revision by Anesthesia & Analgesia*
- MHSRS Abstract: Lizdas D, Avari K, Zimmerman M, Lampotang S - “Medical Modeling & Simulation-Based Assessment – An editor to create integrated tutors for a modular set of mixed reality simulators” This abstract was also submitted and presented at the University of Florida’s Department of Anesthesiology’s Celebration of Research.

- MHSRS Abstract: Zimmerman M, Lizdas D, Avari K, Ihnatsenka B, Lampotang S - *“Military Medical Modeling & Simulation Applications of Medical Technology ‘Realities’ to improve training effectiveness – Deployed clinician self-study and self-debriefing in austere environments: An integrated tutor for a mixed reality simulator of thoracic regional anesthesia”*. This abstract was also submitted and presented at the University of Florida’s Department of Anesthesiology’s Celebration of Research.
- MHSRS Abstract: Lampotang S, Lizdas D, Sappenfield J, Robinson A, Cooper LA - *“Military Medical Modeling & Simulation Applications of medical technology “realities” to improve training effectiveness – 3D visualization improves supraclavicular access to the subclavian vein in a mixed reality simulator”* This abstract was also submitted and presented at the University of Florida’s Department of Anesthesiology’s Celebration of Research.
- ASA Abstract – Sappenfield J, Cooper LA, Lizdas DE, Gravenstein N, Robinson A, Lampotang S *“Visual Augmentation Improves Supraclavicular Access to the Subclavian Vein in a Mixed Reality Simulator”*
- IMSH Abstract: Lampotang S, Sezer TA, Lizdas DE, Sezer B, Cooper LA – *“Cross-Sectional Literacy Trainer: Baseline Assessment of Medical Students”*
- University of Florida’s College of Medicine Celebration of Research Abstract – *“Integrated tutor facilitating curriculum training with a mixed reality simulator for thoracic epidural and thoracic paravertebral blocks”*
- RA Simulator TPVB Curriculum was uploaded to the Department of Anesthesiology’s Bridge website with password protection <http://bridge.ufhealth.org/com-anest/research/study-materials/>
- RA Simulator TPVB Curriculum uploaded to VAM website <http://vam.anest.ufl.edu/rastudy2016/>
- SMARTS SDK: We have created a Software Development Kit for our modular mixed reality platform that allows clients outside our lab to build custom simulations using our hardware and software platform. The SDK is currently in alpha stage development and is used internally in our lab for developing new simulators.

Year 2 (8/1/2015-7/31/2016)

Number of peer-reviewed publications (include ones that are pending publication): 6

MHSRS Abstract: 1

ASA Abstract: 1

UFCOM Celebration of Research: 1

IMSH 2016 DOD Interactive Demo Abstract: 1

ASRA Abstract: 1

- 1 abstract presented 8/19/15 at Military Health System Research Symposium (MHSRS) meeting
- In Progress Review (IPR) presented at TATRC offices, Ft. Detrick, MD on 3/29/2016
- 90-minute workshop on simulator design presented at Medicine X Ed, Stanford on 9/24/2015.

- RA simulator used in hands-on workshops at Moffitt Cancer Center, Tampa, FL on 10/3 and 10/4
- 1 abstract on RA simulator helping to develop modified TPVB technique presented 10/26/15 at American Society of Anesthesiologists (ASA) annual meeting, San Diego, CA
- 1 scientific exhibit presented for 3 consecutive days (10/24-10/26/15) at ASA annual meeting
- RA simulator used in Teleflex booth for 3 days (10/24-10/26/15) at ASA annual meeting
- RA simulator used in JAVMed booth for 3 days (10/24-10/26/15) at ASA annual meeting
- RA simulator used in hands-on workshop on 10/27/15 at ASA annual meeting
- A modular set of interoperable tracked tools (needle, ultrasound probe and virtual camera controller/Tangible User Interface) was built and evaluated.
- Dr. Sotomayor, Dr. Lampotang and David Lizdas demoed the CVA, RA and US skills simulators at the Veteran's Health Affairs SimLEARN on 11/24 near Orlando airport
- The RA simulator and Cross-Sectional literacy simulators were evaluated at Naval Medical Center San Diego from October 26, 2015 to mid-December 2015
- Implemented 64-bit plug-in for tracker; the frame rate on the CVA simulator visualization almost doubled as a result of migrating from 32-bit to 64-bit and rendering in Unity 5 instead of 4.
- Submitted on short notice at DoD's request an abstract "SMARTS: MODULAR STAND AND INTEROPERABLE TRACKED TOOLS FOR AUGMENTED REALITY PROCEDURAL SIMULATORS" on 11/18/15 for the IMSH 2016 DoD Interactive Demo Area (Government Corral).
- Dr. Ihnatsenka started preliminary work with residents on study 2014-U-0658 on 12/12/15
- A continuation patent application on mixed reality simulators for blind and guided medical procedures was filed by UF on 12/28/15 as continuation to an original patent filed in 2010 prior to DoD award
- Our augmented reality procedural simulators were selected to be the sole exhibit of the UF College of Medicine at the inauguration ceremonies on 12/2 and 12/3/2015 of the new president of the University of Florida, Dr. Kent Fuchs
- We implemented adequately realistic fluoroscopic (NOT UltraSound) imaging with the 64-bit version of Unity
- Edwards DA, Vazquez R, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real time 3D visualization helps develop a modified technique for accessing the thoracic epidural space; abstract submitted to ASRA on 12/31/15
- An 85% scale, mirrored, 3D-printed spine that is part of the protocol for the RA simulator learning outcomes study was received 1/7/16
- A provisional patent on cognitive aids (UF1220) was converted to a utility patent on 1/11/16
- The first draft of the needs assessment for the chest tube insertion simulator was completed by Dr. Choi on 1/15/16 based on a simulator needs assessment template created by Dr. Lampotang
- The redesign of the central venous access (CVA) simulator to fit the modular mount was completed
- Small form factor DoD CVA simulator anatomical block was finalized and 3D printed on 1/5/16
- A quick-release mechanism for locking different anatomical blocks to a SMARTS stand was implemented.
- All simulators were rewired with shielded wire to harden against interference from random electrical noise
- Lampotang, Lizdas, Freytes demoed the modular sims to a potential industry licensee on 10/21/2015

- Edwards DA, Vazquez R, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real-time 3D visualization helps develop a modified technique for accessing the thoracic epidural space; abstract submitted to ASRA, 12/31/15
- 3/18-19/16 – Army RA workshop, Baltimore
- 4/18-24 – Evaluation of RA simulator at Walter Reed (Led by Cdr. Michael Kent, MD, USN)
- 4/20/16 – Two PowerPoint presentations by Dr. Barys Ihnatsenka for use with our RA simulator were posted online at http://simulation.health.ufl.edu/education/Curriculum1_lecture_B-1.pptx; and http://simulation.health.ufl.edu/education/Curriculum1_lecture_A-1.pptx
- Mike Kent demoed RA simulator to 6 residents and 4 staff members at Walter Reed
- Brooke Army Medical Center evaluation of CVA simulator by administration director Robert Coffman and Colonel McFarland
- CVA Simulator evaluation in a simulator workshop at Villanova by Major Scully
- CVA simulator evaluation at Wilmington Delaware VAMC by Major Scully
- Received 17 Post-Simulator training surveys from Villanova; simulator returned to UF on 5/17/16.

Year 1 (8/1/2014-7/31/2015)

- Lampotang S, Lizdas DE, Ihnatsenka B: Basics of US in RA. Proceedings of the World Congress of Regional Anesthesia and Pain Therapy (WCRAFT), 2014
- Lampotang S, Lizdas DE, Ihnatsenka B: A mixed reality simulator of thoracic RA. Proceedings of the World Congress of Regional Anesthesia and Pain Therapy (WCRAFT), 2014
- Lampotang S, Le-Wendling L, Coleman CJ, Lizdas DE, Ihnatsenka BI: Real-time 3D visualization in a mixed simulator helps develop a modified regional anesthesia technique. Submitted 3/6/15 to Simulation in Healthcare; favorable review received 5/20/15; need to split manuscript into 3 publications; acknowledgement of federal support (yes).
- Ihnatsenka B, Le-Wendling L, Coleman CJ, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real-time 3D visualization helps develop a modified thoracic paravertebral block, Submitted 4/6/15 to American Society of Anesthesiologists (ASA) 2015 annual meeting; accepted 6/18/15 for poster presentation
<http://www.asaabstracts.com/strands/asaabstracts/printAbstract.htm?jsessionid=698B518CD51AFF97B17E7A229AA125D0?index=0&year=2015&absnum=4398&type=search>
- Lampotang S, Lizdas DE, Cooper LA, Gravenstein N, Ihnatsenka B: A cross-sectional literacy and ultrasound skills trainer. Scientific & Educational Exhibit submitted 4/6/15 to American Society of Anesthesiologists 2015 annual meeting; accepted for presentation as a Scientific & Educational Exhibit on 3 consecutive days (10/24-10/26/2015) at the San Diego Convention Center
- Lampotang S, Lizdas DE, Cooper LA, Gravenstein N, Robinson A: Mixed Reality Simulation for Training Reservists and Military Medical Personnel in Subclavian Central Venous Access, submitted 4/7/15 to Military Health System Research Symposium (MHSRS); presented by Samsun Lampotang, PhD as a poster at the Military Health System Research Symposium (MHSRS) on 8/19/2015, Marriott Hotel, Ft. Lauderdale, FL
- Lampotang, Lizdas, Ihnatsenka: A mixed reality simulator of thoracic regional anesthesia. Exhibited at UF BME PhD Recruitment day (2/20/15)
- Ihnatsenka B, Le-Wendling L, Coleman CJ, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real-time 3D visualization helps develop a modified thoracic paravertebral block. Exhibited at Dept. of Anesthesiology Celebration of Research (4/29/15)

- Lampotang S, Lizdas DE, Cooper LA, Gravenstein N, Ihnatsenka B: A cross-sectional literacy and ultrasound skills trainer. Exhibited at Dept. of Anesthesiology Celebration of Research (4/29/15) – Oral presentation
- 3rd place award for oral presentation of “A cross-sectional literacy and ultrasound skills trainer” at the University of Florida Anesthesiology Department’s Celebration of Research 4/29/15
- Lampotang S, Lizdas DE, Cooper LA, Gravenstein N, Robinson A: Mixed Reality Simulation for Training Reservists and Military Medical Personnel in Subclavian Central Venous Access. Exhibited at Dept. of Anesthesiology Celebration of Research (4/29/15)
- A video of the new RA simulator design was uploaded to the web at http://simulation.health.ufl.edu/research/ra_sim.wmv
- A modified technique for US-guided thoracic paravertebral block (TPVB), the Sagittal Paramedian Oblique technique was developed with the help of the 3D visualization in the RA simulator; a peer-reviewed Empirical Investigation paper was submitted on 3/6/15 to the journal Simulation in Healthcare to describe this potential first in simulation
- A US provisional patent application: Lampotang, Lizdas, Ihnatsenka: “Simulation Features Combining Mixed Reality and Modular Tracking” was filed on 1/10/15 and assigned Serial No. 62/101,997 UF.1220P (UF#15508) prior to the Government Corral exhibit at IMSH in New Orleans. This patent application served two purposes: protect UF intellectual property (IP) before public disclosure at the Government Corral and establish the IP that was already in UF’s possession before the 8/1/2014 start of the DoD funding.
- A mixed reality cross-sectional literacy and ultrasonography skills trainer was developed as a proof of concept of the flexibility and rapid development platform made possible by a modular stand design with an imbedded tracker. The trainer was exhibited at the Government Corral at IMSH in New Orleans (January 11-13, 2015). The cross-sectional literacy trainer has been accepted as a Scientific & Educational exhibit and will be exhibited on 3 consecutive days (10/24-26/2015) at the October 2015 Annual Meeting of the American Society of Anesthesiologists in San Diego, CA.

PRESENTATIONS:

Year 3 (8/1/2016-7/31/2017)

- UCLA CRESST (National Center for Research on Evaluation, Standards, and Student Testing) Meeting – Hands on demo on 9/20/2016.
- NAVAt (Automated Low Flow Anesthesia & Visual Drug Display Systems) meeting in Aalst, Belgium on 9/24/2016
- UZA (Universitair Ziekenhuis Antwerpen hands on workshop in Antwerp, Belgium on 9/27/2016 by Dr. Lampotang with the ultrasonography skills and SMARTS platform.
- CSSALT Open House Presentation of Simulation – A hands on demo of the ultrasonography skills and SMARTS platform on 10/4/2016
- University of Florida’s College of Medicine Alumni meeting for homecoming (30 people use the ultrasonography skills trainer)
- Ihnatsenka B, Le-Wendling L, Zasimovich Y: Ultrasound Guided Advanced Blocks workshop at the American Society of Anesthesiologists (ASA) 2016 annual meeting on 10/22/2016
- Ihnatsenka B, Le-Wendling L: Peripheral Nerve Blocks: Ultrasound, Simulation, and Stimulation – MOCA endorsed workshop session at the American Society of Anesthesiologists (ASA) 2016 annual meeting on 10/24/2016

- Ihnatsenka B: Peripheral Nerve Blocks: Ultrasound, Simulation, and Stimulation – Peripheral Nerve Blocks, 2 sessions (one in the AM and one in the PM) at the American Society of Anesthesiologists (ASA) 2016 annual meeting on 10/25/2016
- Lampotang S, Lizdas D: Advanced Technology Workshop with the RA and Ultrasonography skills simulators at the American Society of Anesthesiologists (ASA) 2016 annual meeting on 10/22/2016
- Kent M, Lampotang S, Lizdas D: Presentation for the Uniformed Services Society of Anesthesiologists on 10/21/2016 where 35 physicians from the Air Force, Navy, Army, and VA utilized the RA and ultrasonography simulators.
- Lizdas D, DeStephens A, Johnson T - CSSALT Open House Presentation of Simulation hands on demo of the ultrasonography skills simulator and the SMARTS platform on 11/3/2016.
- Ihnatsenka B – Cadaveric Regional Anesthesia Ultrasound Workshop at the Cleveland Clinic Conference on 12/3/2016
- Lampotang S, Lizdas D, Johnson T - IMSH meeting, Government Row, Orlando, FL, January 2017
- Tighe P – Johns Hopkins School of Medicine presentation with the RA simulator
- Tighe P, Zasimovich Y – Medical School Teaching Facility presentation of the RA simulator at the University of Maryland divided into two sessions 2/24/17 and 2/25/17
- Lampotang S, Lizdas D - CSSALT Demonstration for Dr. James Murray from the Royal College of Surgeons in Ireland and Mike Good the Dean of the College of Medicine for the University of Florida with the RA, CVA, and ultrasonography skills simulators on 3/3/2017
- Lampotang S, Johnson T – Catherine Price Laboratory Demo of the simulators on 3/10/2017
- Ihnatsenka B: NYSORA – Advanced Blocks: Thoracic / Paravertebral / Intercostal / Epidural / Caudals in Dubai, UAE on 3/23/2017
- Ihnatsenka B: NYSORA – Blocks for knee surgery workshop utilized the RA, CVA, and ultrasonography simulators in Dubai, UAE on 3/24/2017
- Ihnatsenka B: NYSORA – Gastric, lung, airway ultrasound, transcranial & abdomen workshop in Dubai, UAE on 3/25/2017
- Lampotang S, Lizdas D - CSSALT Open House Presentation of the ultrasonography skills trainer on 3/30/2017 in the Harrell Medical Education Building at the University of Florida.
- Lampotang S, Lizdas D – Presentation of the ultrasonography skills trainer to University of Florida dental students on 3/30/2017
- Ihnatsenka B, Le-Wendling, Zasimovich Y – High-Fidelity Simulator for Thoracic Blocks at 42nd Annual Regional Anesthesiology and Acute Pain Medicine Meeting– 4/6/17
- Ihnatsenka B, Le-Wendling, Zasimovich Y – ASRA – Blocks of the Breast and Thorax at 42nd Annual Regional Anesthesiology and Acute Pain Medicine Meeting– 4/6/17
- Lampotang S - CME Simulation Conference: Cross-Sectional Literacy as a Foundation for Ultrasonography on 4/14/2017
- Zasimovich Y – 7th Annual Cadaver and Ultrasound Workshop Regional Anesthesia and Point of Care Ultrasound at UPENN presentation of the RA simulator on 4/21/2017
- Lampotang S, Lizdas D, DeStephens A, Johnson T – University of Florida’s Department of Anesthesiology’s Celebration of Research with the CVA and RA simulator devices on 5/3/17
- Ihnatsenka B – Mixed Reality Simulator For Teaching Learning Thoracic RA in Chengdu, China – 5/10/17 – 5/22/17
- Ihnatsenka B – Three different Thoracic Regional Anesthesia Workshops “Technical Aspects of Placing Thoracic Epidural” in Chengdu, China – 5/10/17 – 5/22/17

- Ihnatsenka B – University of Wisconsin Department of Anesthesiology Grand Rounds presentation of the RA simulator on 7/18/2017

Year 2 (8/1/2015-7/31/2016)

- *Mixed Reality Simulation for Training Reservists and Military Personnel in Subclavian Central Venous Access, Poster MHSRS-15-0857 presented at the Military Health System Research Conference 2015, Ft. Lauderdale, Florida, 8/19/2015*
- *Ihnatsenka B, Le-Wendling L, Coleman CJ, Lizdas DE, Lampotang S: A mixed reality simulator augmented with real-time 3D visualization helps develop a modified thoracic paravertebral block, American Society of Anesthesiologists (ASA) 2015 annual meeting; 10/26/2015*
- *Lampotang, Gravenstein, Ihnatsenka, Lizdas: A cross-sectional literacy and ultrasound skills trainer, Scientific Exhibit, American Society of Anesthesiologists 2015 annual meeting, 10/24-26/2015*
- *Lampotang: 90-minute workshop on simulator design, Stanford Medicine X Ed, Stanford, California, 9/24/2015*
- *Ihnatsenka: taught with the RA simulator, Moffitt Cancer Center, Tampa, FL on 10/3-4/2015*
- *Sotomayor, Lampotang and Lizdas: CVA, RA and US skills simulators, Veteran's Health Affairs SimLEARN, Orlando, Florida, 11/24/2015*
- *Lampotang, Lizdas, DeStephens: Augmented reality procedural simulators were selected to be the sole exhibit of the UF College of Medicine inauguration ceremonies of the new president Dr. Kent Fuchs, Gainesville, Florida, 12/2-3/2015*
- *Lampotang: presented the mixed reality simulator among other technologies at a lecture at the University of Southern California Institute of Creative Technologies (ICT), Los Angeles, California, 1/28/2016*
- *Ihnatsenka: 2 RA and 1 CVA simulators exhibited, GatorRAP, Orlando, FL, 3/5-6/2016*
- *Lampotang: demo of the RA with intelligent tutor, the CVA, the SMARTS platform, Fort Detrick, Maryland, 3/29/16*
- *Ihnatsenka, Demoed RA simulator, American Society for Regional Anesthesia and Pain Medicine, New Orleans, Louisiana, 3/31/16-4/2/16*
- *Zasimovich: demonstrated the RA simulator at workshop, University of Pennsylvania, Philadelphia, Pennsylvania, 4/16/16*
- *Ihnatsenka: Society for Ambulatory Anesthesia, Orlando, Florida, 5/5-7/16*
- *Ihnatsenka: RA Simulator Demonstration, Florida Society for Anesthesiologists, West Palm Beach, Florida, 6/10-12/16*
- *Lampotang: CVA and RA Simulator demonstration at opening of simulation center, Shanghai, China*
- *Lampotang: CVA, RA, and the US-Trainer were used in Mauritius for a clinical workshop, 7/21/16*

Year 1 (8/1/2014-7/31/2015)

- *Lampotang: "Basics of US in Regional Anesthesia" lecture, World Congress of Regional Anesthesia and Pain Therapy, Cape Town International Convention Centre, Cape Town, Republic of South Africa, 11/25/14*
- *Ihnatsenka, Yasimovich, Lampotang: Workshop using UF Regional Anesthesia simulator at Tygerberg Campus of the University of Stellenbosch, Cape Town, RSA, 11/25/14*

- *Lampotang: "A mixed simulator of thoracic regional anesthesia" lecture, World Congress of Regional Anesthesia and Pain Therapy, Cape Town International Convention Centre, Cape Town, Republic of South Africa, 11/26/14*
- *Lampotang, Lizdas: Government Corral exhibit, International Meeting on Simulation in Healthcare, Ernest Morial Convention Center, New Orleans, LA, Jan 2015*
- *David Edwards, MD: RA simulator used at 3 different Harvard workshops at MGH (5/12-17/2014, 2/4/15 and 5/20/15)*
- *Patrick Tighe, MD: Hands-on demonstration of the Regional Anesthesia simulator at the 3rd Annual Acute Pain Medicine and Regional Anesthesia Course, Baltimore, MD, February 14-15, 2015*
- *Lampotang, Lizdas: GatorRAP workshop hands-on session 2/21/15*
- *Lampotang: "A Mixed reality simulator for Cross-Sectional/Ultrasound literacy" lecture, GatorRAP, Gainesville, FL, 2/22/15*
- *Barys Ihnatsenka, MD: lecture, 40th Annual meeting of the American Society of Regional Anesthesia, Las Vegas, NV, 5/16/15*
- *Lampotang: Hands-on workshop with RA and cross-sectional literacy trainers. Geisinger Health System, Danville, PA 6/3/2015*

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

Year 3 (8/1/2016-2017)

Lenny Wade, MS – Assistant Professor of Anesthesiology at Northwestern Medicine whose primary area of research in recent years has been the use of simulation for training medical care givers in their various fields helped to facilitate usage of our RA simulator device amongst residents and faculty members at Northwestern.

David Allan Edwards, MD – Assistant Professor of Anesthesiology at Vanderbilt University Health continues to collaborate with us on loans of our RA simulator since the first year of the project.

Michael Kent, MD – Lieutenant Commander (USN) – Anesthesiologist specializing in Regional Anesthesia for the US Navy for 7 years at Walter Reed.

Brian Fitzgerald, MD – Lieutenant colonel (USAF), Anesthesiology Program Director at San Antonio Uniformed Services Health Education Consortium, Assistant Professor for Uniformed Services University of the Health Sciences - Located in Fort Sam Houston, Texas with 9 years of experience. His specialty is in Anesthesiology and he is affiliated with Brooks Army Medical Center.

Tobias Everett, MBChB, EDRA, FRCA - Sick Kids Hospital (Toronto, Canada) Director of Simulation and Assistant Professor for the Department of Anesthesia who helped with presentation of the regional anesthesia simulator. Dr. Everett has a subspecialty certification in regional anesthesia from the European Society of Regional Anesthesia. Dr. Everett is also the lead of the Simulation Program for the University of Toronto's Department of Anesthesia and has worked with the Royal College of Physicians and Surgeons of Canada as faculty for their National Simulation Education and Training program.

Year 2 (8/1/2015-7/31/2016)

Major Michael Scully, CRNA has been collaborating with us on our simulators. He recently used our RA and CVA simulators at Villanova and at Wilmington Delaware VAMC to train his students.

David Edwards, MD, who has now moved from MGH to Vanderbilt continues to collaborate with us on our RA simulator.

Ascension/NDI is the supplier of the trackers and miniature magnetic 6-DoF sensors used in our mixed reality simulators. Their technical staff provided us with assistance when we had technical questions and extended loan of their latest products for evaluation.

The US Army Research Laboratory's Simulation and Training Technology Center (STTC) is a sub-contractor on the award. Mr. Robert Pike is now our STTC POC and visited our lab on 8/31/16.

Year 1 (8/1/2014-7/31/2015)

David Edwards, MD, an assistant professor at Massachusetts General Hospital (MGH) borrowed our RA simulator for 3 separate mandatory faculty training sessions at MGH (5/12-17/2014; 2/4/15; 5/20/15) Ascension/NDI is the supplier of the trackers and miniature magnetic 6 DoF sensors used in our mixed reality simulators. Their technical staff provided us with assistance when we had technical questions and extended loan of their latest products for evaluation. Our close working relationship with Ascension/NDI is a win-win synergy. We are supplied with the latest products and line of sight of products in the pipeline. In turn, our research is a show case of what can be accomplished with Ascension/NDI products. As an example, Ascension invited us to exhibit our RA simulator at Ascension's booth at IMSH in January 2015.

The US Army Research Laboratory's Simulation and Training Technology Center (STTC) is a sub-contractor on the award.

INTERIM PROGRESS REVIEW

Year 3

The PI, Samsun Lampotang, PhD, was not invited to travel to Ft. Detrick, MD for interim progress review (IPR) for year 3.

Year 2

The PI, Samsun Lampotang, PhD, travelled to Ft. Detrick, MD to present, in person, progress on award W81XWH-14-1-0113 at an In Progress Review on 3/29/2016. As a result, the technical progress report for Quarter 4 is not included in this report because presentation at the IPR waives the need for the Q4 technical progress report.

PUBLICATION, ACKNOWLEDGEMENT, AND PUBLIC RELEASE

The required and relevant annotation was added to publications except in cases where the limited amount of words allowed for abstracts precluded the boilerplate language from being added. We obtained written permission from the program officer in those instances to omit the boilerplate text because of word count restrictions.

A modular set of mixed reality simulators for “blind” and guided procedures

Medical Practice Initiative (MPI) Augmented Reality for Medical Applications (ARM) Log Number 13318017

W81XWH-14-1-0113 Year 3 Quarter 4 (Yr3Q4) Quad Chart



PI: Samsun (Sem) Lampotang, PhD

Org: University of Florida

Award Amount: \$673,157

Study/Product Aim(s)

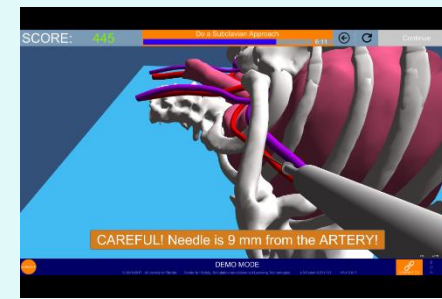
- Needs assessment for a set of 5 procedural mixed simulators
- Build/integrate simulated US imaging into modular sim design
- Design/build/evaluate/refine modular stand
- Design 4 outcome studies (learning, transfer to clinical practice, patient outcomes, return on investment - ROI) w/ UF IRB, HRPO approvals
- Design, build, quality control, deliver Phase 1 RA and CVA simulators to DoD

Approach

The general approach is to design and evaluate the modular design (including the stand, virtual camera tangible user interface, US probe, needle hub) by using the RA and CVA simulators as example applications. Based on needs assessment results, outcome studies will be designed. The Phase I CVA simulator design will be used to conduct and refine initial outcome studies.



Presentation of regional anesthesia simulator at the American Society of Regional Anesthesia meeting



An image of the newly improved and streamlined integrated tutor for the CVA simulator device.

Finalization of Phase I Year 3 of project, awarded Phase II option with a 2 year extension. China Workshops/Presentations, Presentation of RA simulator at the American Society of Regional Anesthesia

Timeline and Cost

Activities	FY15	FY16	FY17
Needs assessment for 5 simulators; Build, integrate simulated US imaging into CVA, RA sims; outcome studies initial design			
Finalize practice, patient, ROI outcome studies designs; start initial learning outcome study on CVA simulator			
Simulator demonstrations; Final design, build, upgrade, quality control, delivery of Phase I CVA and RA simulators to DoD			
Estimated Total Budget (\$K)	236	240	198

Goals/Milestones

CY15 Goals – Needs assessment; design/build RA, CVA simulators

- ☒ Build/Integrate simulated ultrasound guidance to CVA, RA simulators
- ☒ Needs assessment for 5 simulators

CY16 Goals – Validate RA, CVA simulators/Design outcome studies

- ☐ Finalize learning, practice, patient outcome, ROI outcome studies
- ☒ Start initial CVA retrospective patient outcome study data collection through IDR queries

CY17 Goals – Deliver Phase I CVA and RA simulators to DoD

- ☐ Final build and quality control of Phase I CVA & RA simulators

Comments/Challenges/Issues/Concerns

- IRB processing time of legacy paper (not electronic) studies
- Moved end point of study design to Aug 2017

Budget Expenditure to Date

Projected Expenditure: \$674,000

Actual Expenditure: \$664,751 (through 7/31/2017)

Updated: 7/31/2017